



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor
Henrico, Virginia 23233

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Tentative Agenda of Full Board Meeting

July 6, 2021 Meeting

9AM

Board Room 4 (In-person only; no virtual component)

TOPIC

Call to Order: Kris Ratliff

- Welcome & Introductions
- Approval of Agenda

PAGES

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed, this includes the regulations for pharmaceutical processors as that comment period expired on July 5, 2021, or any pending disciplinary matters.

Regulatory: Elaine Yeatts/Caroline Juran

- Adoption of Proposed Regulations Governing Pharmaceutical Processors
 - Summary of Legislative Amendments that May Require Regulatory Action 1-3
 - HB 1988 4-7
 - HB 2218 (Identical to SB 1333) 8-14
 - Notice of Public Comment Period 15-16
 - Summary Chart of Comments that May Warrant Regulatory Action 17-23
 - Comment received from Virginia Medical Cannabis Coalition 24-39
 - Comment received from Dalitso, LLC 40-94
 - Comment received from American Association for Laboratory Accreditation 95
 - Revised Draft of Proposed Regulations (Note: language in yellow reflects proposed language included in the Notice of Public Comment; language in red reflects amendments to proposed language resulting from public comments received as of 6/29/21) 96-172

Consideration of consent orders, summary suspensions, or summary restrictions, if any.

Adjourn

****The Board will have a working lunch at approximately 12pm.****

*****A panel of the Board will convene at 1pm or immediately following adjournment of the board meeting, whichever is later.*****

Summary of Legislative Amendments that May Require Regulatory Action

HB 1988

1. Line 35 = amends telemedicine requirements
2. Line 42 = allows for an “authentic electronic signature” *
3. Line 52 = requires practitioner to hold “sufficient education and training” *
4. Line 54 = removes limitation of patients that may be issued written certification
5. Line 55 = allows board to report unusual patterns of certifications issued *
6. Line 60 = removes requirement to present written certification at processor/dispensary after initial visit for each certificate
7. Line 113 – restricts requirement of PIC to only be in full and actual charge of dispensing area of processor/dispensary
8. Line 124 – changes frequency of routine inspections from quarterly to annually
9. Line 130 = allows for distribution between dispensing facilities
10. Line 131 = allows sale of hemp-based CBD products that pass testing standards
11. Line 138 = directs board to draft regulations for advertising and promotion of processor products and operations, and not limit educational materials to practitioners issuing written certifications and patients
12. Line 142 – removes max number of plants processor may possess at any one time
13. Line 144 – changes disposal of “plant remains” to “agricultural waste”
14. Line 151 – allows processor to remediate cannabis oil that fails any quality testing standard
15. Line 155 – stability testing shall not be required for cannabis oil product with expiration date of 6 months or less
16. Line 159 – limits requirement for pharmacist personal supervision to processor dispensing area and dispensing facility
17. Line 162 – strikes language regarding PIC authorizing employee access to cultivation area and other areas approved by the board
18. Line 164 – “processor” now responsible for adequate security measures to protect cannabis from diversion and PIC has concurrent responsibility for dispensing area
19. Line 167 – requires processor to designate person to have oversight of cultivation and production areas and provide such information to the board
20. Line 171 – clarifies that “material owners” of processor or dispensing facility must submit to background checks *
21. Line 179 – allows criminal background checks of employees and delivery agents to be performed by any service sufficient to disclose federal and state convictions *
22. Line 184 – changes degree in “horticulture” to “field related to the cultivation of plants”
23. Line 189 – allows person with less than two years of experience to perform duties at processor and dispensing facility upon certification as a pharmacy technician
24. Line 194 – limits employee or agent restrictions to felony within last 5 years
25. Line 201 – limits requirement for pharmacist to pharmacy technician ratio to dispensing areas only
26. Line 206 – removes requirement for innovative pilot application prior to using automated process or procedure during production that is otherwise not authorized *

27. Line 237 – authorizes a companion to accompany a patient into the processor’s dispensing area or dispensing facility
28. Line 238 – removes requirement for pharmacist or technician “at the location” to make copy of written certification and allows pharmacist or technician “employed” to perform task and allows copy of certification to be maintained on site or remotely by electronic means *
29. Line 242 – allows viewing of photo ID to be viewed in person or by audiovisual means *
30. Line 245 – allows initial dispensing to be delivered to patient *
31. Line 251 – allows dispensing pharmacist or certifying practitioner to determine what constitutes a 90-day supply
32. Line 252 – removes requirement for board to determine what constitutes a 90-day supply
33. Line 278 – directs board to amend 18VAC110-60-220 and allows board to include reasonable restrictions on advertising, etc. as outlined in enactment clause

*** Subject did not appear to require regulatory action**

HB 2218 and SB 1333

1. Lines 40, 63, and other various lines – changes “cannabis oil” to “cannabis products”
2. Line 132 – introduces new term of “botanical cannabis”
3. Line 141 – introduces new term of “cannabis product”
4. Line 150 – introduces new term of “usable cannabis”
5. Line 159 – requires specific authorization on written certificate or subsequently communicated verbally or in writing to pharmacist if practitioner authorizes dispensing of botanical cannabis to patient who is a minor *
6. Line 216 – expands definition of “pharmaceutical processor” to include allowances for “botanical cannabis, usable cannabis, and cannabis products”
7. Line 235 – directs board to promulgate labeling regulations to include potency of each botanical cannabis product and amount recommended by practitioner or dispensing pharmacist
8. Line 237 – directs board to promulgate regulations for dispensing and delivering “cannabis products”, instead of “cannabis oil”
9. Line 240 – restricts dosage limitation requirement of 10mg of delta-9 THC for each dispensed dose to “cannabis oil” only *
10. Line 242 – allows wholesale distribution of “usable cannabis”, “botanical cannabis”, oil, and “cannabis products”
11. Line 244 – allows sale of devices for administration of “cannabis products”
12. Line 251 – removes requirement for regulations to address maximum number of plants processor may possess at any one time
13. Line 255 – removes requirement for batch from which testing sample of “cannabis product” is obtained to be “homogenized”
14. Line 259 – retains requirement for “cannabis oil” sample to come from “homogenized” batch
15. Line 260 – requires certified testing laboratory to determine minimum sample size from each batch of “botanical cannabis”
16. Line 262 – specifies for what items botanical cannabis must be tested

17. Line 264 – requires testing thresholds to be consistent with generally accepted cannabis industry thresholds
18. Line 265 – allows for remediation of botanical cannabis batch if fails testing
19. Line 267 – allows retested failed botanical cannabis batch to be processed into cannabis oil, unless failure related to pesticide requirements
20. Line 270 – requires any batch processed into cannabis oil to comply with all applicable testing standards
21. Line 310 – retains provision for innovative pilot application for use of automated process or procedure not otherwise authorized in law or regulation
22. Line 322 – requires board to register all cannabis products that meet testing, labeling, and packaging standards
23. Line 342 – allows dispensing of more than one product during 90-day supply
24. Line 343 - restricts dispensing of botanical cannabis to no more than 4 oz. per 30 days
25. Line 346 – in determining appropriate amount to dispense, processor or dispensing facility shall consider all products dispensed and adjust accordingly
26. Line 360 – clarifies that any cannabis product on site may be up to 10% greater than or less than level of delta-9 THC measured for labeling; Line 362 - processor or dispensing facility shall ensure cannabis product on site is within such range; Line 363 – processor shall establish stability testing schedule of cannabis products.
27. Line 368-374 – expands criminal liabilities for processor, dispensing facility, employees, agents *
28. Line 375 – directs board to establish testing standards for botanical cannabis consistent with generally accepted cannabis industry standards
29. Line 377 – exempts promulgation of regulations from Administrative Process Act and requires board to complete its work such that regulations may be implemented by September 1, 2021
30. Line 383 – allows board to assess and collect botanical cannabis regulatory fees from each processor in an amount sufficient to implement first, second, and third enactments (To be addressed later once cost of cannabis-specific software known.)
31. Line 386 – exempts board’s acquisition of cannabis-specific software product from Virginia Public Procurement Act *

*** Subject did not appear to require regulatory action**

2021 SPECIAL SESSION I

ENROLLED

ENROLLED

HB1988ER

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VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to Board of Pharmacy; pharmaceutical processors; processing and dispensing cannabis oil.

[H 1988]

Approved

Be it enacted by the General Assembly of Virginia:
1. That §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3408.3. Certification for use of cannabis oil for treatment.

A. As used in this section:

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include oil from industrial hemp extract acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it has been acquired and formulated with cannabis plant extract by a pharmaceutical processor.

"Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home health services, private provider licensed by the Department of Behavioral Health and Developmental Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances, provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature or authentic electronic signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing the issuance of a certification for the use of cannabis oil for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board and shall hold sufficient education and training to exercise appropriate professional judgment in the certification of patients. The Board shall, in consultation with the Board of Medicine, set a not limit on the number of patients to whom a practitioner may issue a written certification. The Board may report information to the applicable licensing board on unusual patterns of certifications issued by a practitioner.

57 F. A patient who has been issued a written certification shall register with the Board or, if such
58 patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian
59 shall register and shall register such patient with the Board. *No patient shall be required to physically*
60 *present the written certification after the initial dispensing by any pharmaceutical processor or cannabis*
61 *dispensing facility under each written certification, provided that the pharmaceutical processor or*
62 *cannabis dispensing facility maintains an electronic copy of the written certification.*

63 G. A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such
64 patient's parent or legal guardian, may designate an individual to act as his registered agent for the
65 purposes of receiving cannabis oil pursuant to a valid written certification. Such designated individual
66 shall register with the Board. The Board may set a limit on the number patients for whom any
67 individual is authorized to act as a registered agent.

68 H. *Upon delivery of cannabis oil by a pharmaceutical processor or cannabis dispensing facility to a*
69 *designated caregiver facility, any employee or contractor of a designated caregiver facility, who is*
70 *licensed or registered by a health regulatory board and who is authorized to possess, distribute, or*
71 *administer medications, may accept delivery of the cannabis oil on behalf of a patient or resident for*
72 *subsequent delivery to the patient or resident and may assist in the administration of the cannabis oil to*
73 *the patient or resident as necessary.*

74 I. The Board shall promulgate regulations to implement the registration process. Such regulations
75 shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification,
76 the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an
77 incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for
78 ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a
79 prohibition for the patient to be issued a written certification by more than one practitioner during any
80 given time period.

81 J. Information obtained under the registration process shall be confidential and shall not be subject
82 to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However,
83 reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee
84 for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local
85 law enforcement for the purpose of investigating or prosecuting a specific individual for a specific
86 violation of law, (iii) licensed practitioners or pharmacists, *or their agents*, for the purpose of providing
87 patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv)
88 a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered
89 patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated
90 adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to
91 information related to such registered patient.

92 **§ 54.1-3442.5. Definitions.**

93 As used in this article:

94 "Cannabis oil" has the same meaning as specified in § 54.1-3408.3.

95 "Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant
96 to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses
97 cannabis oil produced by a pharmaceutical processor to a registered patient, his registered agent, or, if
98 such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal
99 guardian.

100 "Cannabis oil" has the same meaning as specified in § 54.1-3408.3.

101 "Designated caregiver facility" has the same meaning as defined in § 54.1-3408.3.

102 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to
103 § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil,
104 produces cannabis oil, and dispenses cannabis oil to a registered patient, his registered agent, or, if such
105 patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal
106 guardian.

107 "Practitioner" has the same meaning as specified in § 54.1-3408.3.

108 "Registered agent" has the same meaning as specified in § 54.1-3408.3.

109 **§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

110 A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without first
111 obtaining a permit from the Board. The application for such permit shall be made on a form provided
112 by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical
113 ~~processor~~ *processor's dispensing area* or cannabis dispensing facility. The Board shall establish an
114 application fee and other general requirements for such application.

115 B. Each permit shall expire annually on a date determined by the Board in regulation. The number of
116 permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and
117 up to five cannabis dispensing facilities for each health service area established by the Board of Health.

118 Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and
119 cannabis dispensing facility.

120 C. The Board shall adopt regulations establishing health, safety, and security requirements for
121 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements
122 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum
123 equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) ~~quarterly routine~~
124 inspections *no more frequently than once annually*; (viii) processes for safely and securely dispensing
125 and delivering in person cannabis oil to a registered patient, his registered agent, or, if such patient is a
126 minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix)
127 dosage limitations, which shall provide that each dispensed dose of cannabis oil not exceed 10
128 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the
129 transfer of cannabis oil products between pharmaceutical processors ~~and~~, between a pharmaceutical
130 processor and a cannabis dispensing facility, *and between cannabis dispensing facilities*; (xi) an
131 allowance for the sale of devices for administration of dispensed products *and hemp-based CBD*
132 *products that meet the applicable standards set forth in state and federal law, including the laboratory*
133 *testing standards set forth in subsection M*; (xii) an allowance for the use and distribution of inert
134 product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical
135 processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a
136 written certification; ~~and~~ (xiii) a process for acquiring oil from industrial hemp extract and formulating
137 such oil extract with Cannabis plant extract into allowable dosages of cannabis oil; *and (xiv) an*
138 *allowance for the advertising and promotion of the pharmaceutical processor's products and operations,*
139 *which shall not limit the pharmaceutical processor from the provision of educational material to*
140 *practitioners who issue written certifications and registered patients.* The Board shall also adopt
141 regulations for pharmaceutical processors that include requirements for (a) processes for safely and
142 securely cultivating Cannabis plants intended for producing cannabis oil; (b) ~~a maximum number of~~
143 ~~marijuana plants a pharmaceutical processor may possess at any one time~~; (c) the secure disposal of
144 ~~plant remains; agricultural waste, and~~ (d) (c) a process for registering cannabis oil products.

145 D. The Board shall require that, after processing and before dispensing cannabis oil, a pharmaceutical
146 processor shall make a sample available from each homogenized batch of product for testing by an
147 independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing
148 shall be determined by each laboratory and may vary due to sample matrix, analytical method, and
149 laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing
150 or distribution from each homogenized batch is required to achieve a representative sample for analysis.
151 *The pharmaceutical processor may remediate cannabis oil that fails any quality testing standard.*
152 *Following remediation, all remediated cannabis oil shall be subject to laboratory testing and approved*
153 *upon satisfaction of testing standards applied to cannabis oil generally. Stability testing shall not be*
154 *required for any cannabis oil product with an expiration date assigned by the pharmaceutical processor*
155 *of six months or less from the date of packaging.*

156 E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances
157 registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the
158 Board in regulation.

159 F. Every pharmaceutical ~~processor~~ *processor's dispensing area* or cannabis dispensing facility shall
160 be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical
161 processor or cannabis dispensing facility. ~~A pharmacist in charge of a pharmaceutical processor may~~
162 ~~authorize certain employee access to secured areas designated for cultivation and other areas approved~~
163 ~~by the Board. No pharmacist shall be required to be on the premises during such authorized access. The~~
164 ~~pharmacist in charge~~ *The pharmaceutical processor shall ensure that security measures are adequate to*
165 *protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have concurrent*
166 *responsibility for preventing diversion from the dispensing area.*

167 *Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation*
168 *and production areas of the pharmaceutical processor and shall provide such information to the Board.*
169 *The Board shall direct all communications related to enforcement of requirements related to cultivation*
170 *and production of cannabis oil products by the pharmaceutical processor to such designated person.*

171 G. The Board shall require *the material owners of an applicant* for a pharmaceutical processor or
172 cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive
173 information to be forwarded along with his fingerprints through the Central Criminal Records Exchange
174 to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information
175 regarding the ~~applicant~~ *applicant's material owners*. The cost of fingerprinting and the criminal history
176 record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the
177 results of the criminal history background check to the Board or its designee, which shall be a
178 governmental entity. *A pharmaceutical processor shall maintain evidence of criminal background checks*

240 employed by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on
 241 site or remotely by electronic means, for two years a paper or electronic copy of the written certification
 242 that provides an exact image of the document that is clearly legible; shall view, *in person or by*
 243 *audiovisual means*, a current photo identification of the patient, registered agent, parent, or legal
 244 guardian; and shall verify current board registration of the practitioner and the corresponding patient,
 245 registered agent, parent, or legal guardian. *Thereafter, an initial dispensing may be delivered to the*
 246 *patient, registered agent, parent, legal guardian, or designated caregiver facility.* Prior to any
 247 subsequent dispensing of cannabis oil pursuant to each written certification, ~~the pharmacist, pharmacy~~
 248 ~~technician, an employee~~ or delivery agent shall view ~~the current written certification~~; a current photo
 249 identification of the patient, registered agent, parent, or legal guardian; and the current board registration
 250 issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor or cannabis
 251 dispensing facility shall dispense more than a 90-day supply, *as determined by the dispensing*
 252 *pharmacist or certifying practitioner*, for any patient during any 90-day period. ~~The Board shall establish~~
 253 ~~in regulation an amount of cannabis oil that constitutes a 90-day supply to treat or alleviate the~~
 254 ~~symptoms of a patient's diagnosed condition or disease.~~ *A pharmaceutical processor or cannabis*
 255 *dispensing facility may dispense less than a 90-day supply.*

256 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis oil that
 257 has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board
 258 or cannabis oil that has been formulated with oil from industrial hemp acquired by a pharmaceutical
 259 processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A
 260 pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

261 C. The Board shall report annually by December 1 to the Chairmen of the House Committee for
 262 ~~Courts of Justice~~ *Health, Welfare and Institutions* and the Senate Committee on ~~the Judiciary~~ *Education*
 263 *and Health* on the operation of pharmaceutical processors and cannabis dispensing facilities issued a
 264 permit by the Board, including the number of practitioners, patients, registered agents, and parents or
 265 legal guardians of patients who have registered with the Board and the number of written certifications
 266 issued pursuant to § 54.1-3408.3.

267 D. The concentration of delta-9-tetrahydrocannabinol in any cannabis oil on site may be up to 10
 268 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A
 269 pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any
 270 cannabis oil on site is within such range. A pharmaceutical processor producing cannabis oil shall
 271 establish a stability testing schedule of cannabis oil.

272 **2. That the Board of Pharmacy (the Board) shall promulgate regulations implementing the**
 273 **provisions of this act. The Board's initial adoption of regulations shall be exempt from the**
 274 **Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board shall**
 275 **provide an opportunity for public comment on the regulations prior to adoption. The Board shall**
 276 **complete work on such regulations in order that they will be implemented no later than**
 277 **September 1, 2021.**

278 **3. That in promulgating the regulations implementing the provisions of this act, the Board of**
 279 **Pharmacy shall amend 18VAC-110-60-220 and may include reasonable restrictions on the**
 280 **advertising, logos, signage, and display of cannabis oil products and the appearance of**
 281 **pharmaceutical processors and cannabis dispensing facilities, provided that such restrictions do not**
 282 **prohibit (i) the reasonable promotion of their business and operations or (ii) nonpublic**
 283 **communications. Restrictions may include (a) prohibiting false or misleading statements, (b)**
 284 **prohibiting incorporating unsupported health claims, (c) prohibiting advertisements that target**
 285 **children and the use of statements and illustrations designed or likely to appeal to children, (d)**
 286 **prohibiting online advertising intended to target or otherwise appeal to children, (e) restricting the**
 287 **proximity of advertising to schools, and (f) restricting the posting of advertisements on public**
 288 **property, including public transit vehicles and facilities.**

2021 SPECIAL SESSION I

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HB218ER

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VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 18.2-250.1, 54.1-2519, 54.1-2521, 54.1-2903, 54.1-3408.3, and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to pharmaceutical processors; cannabis products.

[H 2218]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 54.1-2519, 54.1-2521, 54.1-2903, 54.1-3408.3, and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia are amended and reenacted as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.). The attorney for the Commonwealth or the county, city, or town attorney may prosecute such a case.

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is subject to a civil penalty of no more than \$25. A violation of this section is a civil offense. Any civil penalties collected pursuant to this section shall be deposited into the Drug Offender Assessment and Treatment Fund established pursuant to § 18.2-251.02.

B. Any violation of this section shall be charged by summons. A summons for a violation of this section may be executed by a law-enforcement officer when such violation is observed by such officer. The summons used by a law-enforcement officer pursuant to this section shall be in form the same as the uniform summons for motor vehicle law violations as prescribed pursuant to § 46.2-388. No court costs shall be assessed for violations of this section. A person's criminal history record information as defined in § 9.1-101 shall not include records of any charges or judgments for a violation of this section, and records of such charges or judgments shall not be reported to the Central Criminal Records Exchange. However, if a violation of this section occurs while an individual is operating a commercial motor vehicle as defined in § 46.2-341.4, such violation shall be reported to the Department of Motor Vehicles and shall be included on such individual's driving record.

C. The procedure for appeal and trial of any violation of this section shall be the same as provided by law for misdemeanors; if requested by either party on appeal to the circuit court, trial by jury shall be as provided in Article 4 (§ 19.2-260 et seq.) of Chapter 15 of Title 19.2, and the Commonwealth shall be required to prove its case beyond a reasonable doubt.

D. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

E. The provisions of this section involving marijuana in the form of cannabis ~~or~~ products as that term is defined in § 54.1-3408.3 shall not apply to any person who possesses such ~~or~~ cannabis product pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the person's diagnosed condition or disease, (ii) if such person is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease, or (iii) if such person has been designated as a registered agent pursuant to § 54.1-3408.3, the diagnosed condition or disease of his principal or, if the principal is the parent or legal guardian of a minor or of an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease.

§ 54.1-2519. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug

57 Diversion Unit.

58 "Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of
59 the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

60 "Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled
61 substances included in Schedule V for which a prescription is required; naloxone; and all drugs of
62 concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter.
63 "Covered substance" also includes cannabis ~~or~~ *products* dispensed by a pharmaceutical processor in
64 Virginia.

65 "Department" means the Virginia Department of Health Professions.

66 "Director" means the Director of the Virginia Department of Health Professions.

67 "Dispense" means to deliver a controlled substance to an ultimate user, research subject, or owner of
68 an animal patient by or pursuant to the lawful order of a practitioner, including the prescribing and
69 administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

70 "Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or
71 to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered
72 substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who
73 dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

74 "Drug of concern" means any drug or substance, including any controlled substance or other drug or
75 substance, where there has been or there is the potential for abuse and that has been identified by the
76 Board of Pharmacy pursuant to § 54.1-3456.1.

77 "Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to
78 §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in
79 another state to so issue a prescription for a covered substance.

80 "Recipient" means a person who receives a covered substance from a dispenser and includes the
81 owner of an animal patient.

82 "Relevant health regulatory board" means any such board that licenses persons or entities with the
83 authority to prescribe or dispense covered substances, including the Board of Dentistry, the Board of
84 Medicine, the Board of Veterinary Medicine, and the Board of Pharmacy.

85 **§ 54.1-2521. Reporting requirements.**

86 A. The failure by any person subject to the reporting requirements set forth in this section and the
87 Department's regulations to report the dispensing of covered substances shall constitute grounds for
88 disciplinary action by the relevant health regulatory board.

89 B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the
90 following information:

91 1. The recipient's name and address.

92 2. The recipient's date of birth.

93 3. The covered substance that was dispensed to the recipient.

94 4. The quantity of the covered substance that was dispensed.

95 5. The date of the dispensing.

96 6. The prescriber's identifier number and, in cases in which the covered substance is *a cannabis or*
97 *product*, the expiration date of the written certification.

98 7. The dispenser's identifier number.

99 8. The method of payment for the prescription.

100 9. Any other non-clinical information that is designated by the Director as necessary for the
101 implementation of this chapter in accordance with the Department's regulations.

102 10. Any other information specified in regulations promulgated by the Director as required in order
103 for the Prescription Monitoring Program to be eligible to receive federal funds.

104 C. Except as provided in subdivision 7 of § 54.1-2522, in cases where the ultimate user of a covered
105 substance is an animal, the dispenser shall report the relevant information required by subsection B for
106 the owner of the animal.

107 D. The reports required herein shall be made to the Department or its agent within 24 hours or the
108 dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner
109 and format and according to the standards and schedule established in the Department's regulations.

110 **§ 54.1-2903. What constitutes practice; advertising in connection with medical practice.**

111 A. Any person shall be regarded as practicing the healing arts who actually engages in such practice
112 as defined in this chapter, or who opens an office for such purpose, or who advertises or announces to
113 the public in any manner a readiness to practice or who uses in connection with his name the words or
114 letters "Doctor," "Dr.," "M.D.," "D.O.," "D.P.M.," "D.C.," "Healer," "N.P.," or any other title, word,
115 letter or designation intending to designate or imply that he is a practitioner of the healing arts or that
116 he is able to heal, cure or relieve those suffering from any injury, deformity or disease.

117 Signing a birth or death certificate, or signing any statement certifying that the person so signing has

118 rendered professional service to the sick or injured, or signing or issuing a prescription for drugs or
 119 other remedial agents, shall be prima facie evidence that the person signing or issuing such writing is
 120 practicing the healing arts within the meaning of this chapter except where persons other than physicians
 121 are required to sign birth certificates.

122 B. No person regulated under this chapter shall use the title "Doctor" or the abbreviation "Dr." in
 123 writing or in advertising in connection with his practice unless he simultaneously uses words, initials, an
 124 abbreviation or designation, or other language that identifies the type of practice for which he is
 125 licensed. No person regulated under this chapter shall include in any advertisement a reference to
 126 marijuana, as defined in § 18.2-247, unless such advertisement is for the treatment of addiction or
 127 substance abuse. However, nothing in this subsection shall prevent a person from including in any
 128 advertisement that such person is registered with the Board of Pharmacy to issue written certifications
 129 for the use of cannabis ~~oil~~ *products*, as defined in § 54.1-3408.3.

130 **§ 54.1-3408.3. Certification for use of cannabis products for treatment.**

131 A. As used in this section:

132 "*Botanical cannabis*" means *cannabis* that is composed wholly of usable *cannabis* from the same
 133 *parts of the same chemovar of cannabis plant*.

134 "*Cannabis oil*" means any formulation of processed Cannabis plant extract, which may include oil
 135 from industrial hemp extract acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a
 136 dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or
 137 tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of delta-9-tetrahydrocannabinol
 138 per dose. "*Cannabis oil*" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt,
 139 or processed in compliance with state or federal law, unless it has been acquired and formulated with
 140 cannabis plant extract by a pharmaceutical processor.

141 "*Cannabis product*" means a product that is (i) produced by a pharmaceutical processor, registered
 142 with the Board, and compliant with testing requirements and (ii) composed of cannabis oil or botanical
 143 *cannabis*.

144 "*Practitioner*" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a
 145 physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the
 146 Board of Medicine and the Board of Nursing.

147 "*Registered agent*" means an individual designated by a patient who has been issued a written
 148 certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated
 149 by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

150 "*Usable cannabis*" means any *cannabis plant material*, including seeds, but not (i) resin that has
 151 been extracted from any part of the *cannabis plant*, its seeds, or its resin; (ii) the mature stalks, fiber
 152 produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or
 153 preparation of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

154 B. A practitioner in the course of his professional practice may issue a written certification for the
 155 use of cannabis ~~oil~~ *products* for treatment or to alleviate the symptoms of any diagnosed condition or
 156 disease determined by the practitioner to benefit from such use. The practitioner shall use his
 157 professional judgment to determine the manner and frequency of patient care and evaluation and may
 158 employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II
 159 through V controlled substances. *If a practitioner determines it is consistent with the standard of care to*
 160 *dispense botanical cannabis to a minor, the written certification shall specifically authorize such*
 161 *dispensing. If not specifically included on the initial written certification, authorization for botanical*
 162 *cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.*

163 C. The written certification shall be on a form provided by the Office of the Executive Secretary of
 164 the Supreme Court developed in consultation with the Board of Medicine. Such written certification
 165 shall contain the name, address, and telephone number of the practitioner, the name and address of the
 166 patient issued the written certification, the date on which the written certification was made, and the
 167 signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no
 168 later than one year after its issuance unless the practitioner provides in such written certification an
 169 earlier expiration.

170 D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing
 171 cannabis ~~oil~~ *products* for the treatment or to alleviate the symptoms of a patient's diagnosed condition or
 172 disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall
 173 preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a
 174 patient's medical condition or otherwise violating the applicable standard of care for evaluating or
 175 treating medical conditions.

176 E. A practitioner who issues a written certification to a patient pursuant to this section shall register
 177 with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number
 178 of patients to whom a practitioner may issue a written certification.

179 F. A patient who has been issued a written certification shall register with the Board or, if such
 180 patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian
 181 shall register and shall register such patient with the Board.

182 G. A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such
 183 patient's parent or legal guardian, may designate an individual to act as his registered agent for the
 184 purposes of receiving cannabis ~~oil~~ *products* pursuant to a valid written certification. Such designated
 185 individual shall register with the Board. The Board may set a limit on the number of patients for whom
 186 any individual is authorized to act as a registered agent.

187 H. The Board shall promulgate regulations to implement the registration process. Such regulations
 188 shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification,
 189 the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an
 190 incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for
 191 ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a
 192 prohibition for the patient to be issued a written certification by more than one practitioner during any
 193 given time period.

194 I. Information obtained under the registration process shall be confidential and shall not be subject to
 195 the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However,
 196 reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee
 197 for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local
 198 law enforcement for the purpose of investigating or prosecuting a specific individual for a specific
 199 violation of law, (iii) licensed practitioners or pharmacists for the purpose of providing patient care and
 200 drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a
 201 pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered patient,
 202 or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as
 203 defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related
 204 to such registered patient.

205 § 54.1-3442.5. Definitions.

206 As used in this article:

207 "~~Cannabis oil~~" has "*Botanical cannabis,*" "*cannabis oil,*" "*cannabis product,*" and "*usable cannabis*"
 208 have the same ~~meaning~~ *meanings* as specified in § 54.1-3408.3.

209 "Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant
 210 to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses
 211 cannabis ~~oil~~ *products* produced by a pharmaceutical processor to a registered patient, his registered
 212 agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's
 213 parent or legal guardian.

214 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to
 215 § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil,
 216 *botanical cannabis,* and *usable cannabis,* produces cannabis ~~oil~~ *products,* and dispenses cannabis ~~oil~~
 217 *products* to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated
 218 adult as defined in § 18.2-369, such patient's parent or legal guardian.

219 "Practitioner" has the same meaning as specified in § 54.1-3408.3.

220 "Registered agent" has the same meaning as specified in § 54.1-3408.3.

221 § 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.

222 A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without first
 223 obtaining a permit from the Board. The application for such permit shall be made on a form provided
 224 by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical
 225 processor or cannabis dispensing facility. The Board shall establish an application fee and other general
 226 requirements for such application.

227 B. Each permit shall expire annually on a date determined by the Board in regulation. The number of
 228 permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and
 229 up to five cannabis dispensing facilities for each health service area established by the Board of Health.
 230 Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and
 231 cannabis dispensing facility.

232 C. The Board shall adopt regulations establishing health, safety, and security requirements for
 233 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements
 234 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum
 235 equipment and resources; (v) recordkeeping; (vi) labeling, *including the potency of each botanical*
 236 *cannabis product and the amounts recommended by the practitioner or dispensing pharmacist,* and
 237 packaging; (vii) quarterly inspections; (viii) processes for safely and securely dispensing and delivering
 238 in person cannabis ~~oil~~ *products* to a registered patient, his registered agent, or, if such patient is a minor
 239 or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) dosage

240 limitations, which shall for cannabis oil that provide that each dispensed dose of cannabis oil not exceed
 241 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the
 242 transfer of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between
 243 pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility;
 244 (xi) an allowance for the sale of devices for administration of dispensed cannabis products; (xii) an
 245 allowance for the use and distribution of inert product samples containing no cannabinoids for patient
 246 demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for
 247 further distribution or sale, without the need for a written certification; and (xiii) a process for acquiring
 248 oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract into
 249 allowable dosages of cannabis oil. The Board shall also adopt regulations for pharmaceutical processors
 250 that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended
 251 for producing cannabis oil products; ~~(b) a maximum number of marijuana plants a pharmaceutical~~
 252 ~~processor may possess at any one time;~~ (e) ~~(b)~~ the secure disposal of plant remains; and ~~(d)~~ (c) a
 253 process for registering cannabis oil products.

254 D. The Board shall require that, after processing and before dispensing any cannabis oil products, a
 255 pharmaceutical processor shall make a sample available from each homogenized batch of cannabis
 256 product for testing by an independent laboratory located in Virginia meeting Board requirements. A
 257 valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix,
 258 analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of
 259 individual units for dispensing or distribution from each homogenized batch of cannabis oil is required
 260 to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined
 261 by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a
 262 representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested
 263 for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide
 264 chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing
 265 thresholds shall be consistent with generally accepted cannabis industry thresholds. If a sample from a
 266 batch of botanical cannabis fails testing requirements, the processor may remediate the batch and
 267 submit a sample for retesting. If the batch fails retesting, it shall be considered usable cannabis and
 268 may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case
 269 the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any
 270 batch processed into cannabis oil shall comply with all applicable testing standards.

271 E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances
 272 registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the
 273 Board in regulation.

274 F. Every pharmaceutical processor or cannabis dispensing facility shall be under the personal
 275 supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis
 276 dispensing facility. A pharmacist in charge of a pharmaceutical processor may authorize certain
 277 employee access to secured areas designated for cultivation and other areas approved by the Board. No
 278 pharmacist shall be required to be on the premises during such authorized access. The
 279 pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion
 280 at all times.

281 G. The Board shall require an applicant for a pharmaceutical processor or cannabis dispensing
 282 facility permit to submit to fingerprinting and provide personal descriptive information to be forwarded
 283 along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of
 284 Investigation for the purpose of obtaining criminal history record information regarding the applicant.
 285 The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The
 286 Central Criminal Records Exchange shall forward the results of the criminal history background check to
 287 the Board or its designee, which shall be a governmental entity.

288 H. In addition to other employees authorized by the Board, a pharmaceutical processor may employ
 289 individuals who may have less than two years of experience (i) to perform cultivation-related duties
 290 under the supervision of an individual who has received a degree in horticulture or a certification
 291 recognized by the Board or who has at least two years of experience cultivating plants and (ii) to
 292 perform extraction-related duties under the supervision of an individual who has a degree in chemistry
 293 or pharmacology or at least two years of experience extracting chemicals from plants.

294 I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to
 295 five cannabis dispensing facilities for the dispensing of cannabis oil products that has have been
 296 cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each
 297 cannabis dispensing facility shall be located within the same health service area as the pharmaceutical
 298 processor.

299 J. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another
 300 jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or

301 Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the
 302 laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor or
 303 cannabis dispensing facility.

304 K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for
 305 pre-employment drug screening and regular, ongoing, random drug screening of employees.

306 L. A pharmacist at the pharmaceutical processor and the cannabis dispensing facility shall determine
 307 the number of pharmacy interns, pharmacy technicians and pharmacy technician trainees who can be
 308 safely and competently supervised at one time; however, no pharmacist shall supervise more than six
 309 persons performing the duties of a pharmacy technician at one time.

310 M. Any person who proposes to use an automated process or procedure during the production of
 311 cannabis ~~oil~~ *products* that is not otherwise authorized in law or regulation or at a time when a
 312 pharmacist will not be ~~on-site~~ *on site* may apply to the Board for approval to use such process or
 313 procedure pursuant to subsections B through E of § 54.1-3307.2.

314 N. A pharmaceutical processor may acquire oil from industrial hemp extract processed in Virginia,
 315 and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A
 316 pharmaceutical processor may process and formulate such oil extract with cannabis plant extract into an
 317 allowable dosage of cannabis oil. Oil from industrial hemp acquired by a pharmaceutical processor is
 318 subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing
 319 shall be performed by a laboratory located in Virginia and in compliance with state law. The industrial
 320 hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor
 321 before oil from industrial hemp may be acquired.

322 O. *The Board shall register all cannabis products that meet testing, labeling, and packaging*
 323 *standards.*

324 **§ 54.1-3442.7. Dispensing cannabis products; report.**

325 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis ~~oil~~
 326 *products* only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as
 327 made evident to the Board, has been issued a valid written certification, and is registered with the Board
 328 pursuant to § 54.1-3408.3; (ii) such patient's registered agent; or (iii) if such patient is a minor or an
 329 incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia
 330 resident or temporarily resides in Virginia as made evident to the Board and is registered with the Board
 331 pursuant to § 54.1-3408.3. Prior to the initial dispensing of each written certification, the pharmacist or
 332 pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall
 333 make and maintain for two years a paper or electronic copy of the written certification that provides an
 334 exact image of the document that is clearly legible; shall view a current photo identification of the
 335 patient, registered agent, parent, or legal guardian; and shall verify current board registration of the
 336 practitioner and the corresponding patient, registered agent, parent, or legal guardian. Prior to any
 337 subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery
 338 agent shall view the current written certification; a current photo identification of the patient, registered
 339 agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent,
 340 parent, or legal guardian. No pharmaceutical processor or cannabis dispensing facility shall dispense
 341 more than a 90-day supply of a *cannabis product* for any patient during any 90-day period; *however, a*
 342 *pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product*
 343 *to a patient at one time. No more than four ounces of botanical cannabis shall be dispensed for each*
 344 *30-day period for which botanical cannabis is dispensed.* The Board shall establish in regulation an
 345 amount of cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's
 346 diagnosed condition or disease. *In determining the appropriate amount of a cannabis product to be*
 347 *dispensed to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all*
 348 *cannabis products dispensed to the patient and adjust the amount dispensed accordingly.*

349 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis ~~oil that~~
 350 ~~has been cultivated and~~ *products* produced on the premises of a pharmaceutical processor permitted by
 351 the Board or cannabis oil that has been formulated with oil from industrial hemp acquired by a
 352 pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to
 353 § 54.1-3442.6. A pharmaceutical processor may begin cultivation upon being issued a permit by the
 354 Board.

355 C. The Board shall report annually by December 1 to the Chairmen of the House Committee for
 356 Courts of Justice and the Senate Committee on the Judiciary on the operation of pharmaceutical
 357 processors and cannabis dispensing facilities issued a permit by the Board, including the number of
 358 practitioners, patients, registered agents, and parents or legal guardians of patients who have registered
 359 with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

360 D. The concentration of delta-9-tetrahydrocannabinol in any cannabis ~~oil~~ *product* on site may be up
 361 to 10 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A

362 pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any
363 cannabis ~~or~~ *product* on site is within such range. A pharmaceutical processor producing cannabis ~~or~~
364 *products* shall establish a stability testing schedule of cannabis ~~or~~ *products*.

365 **§ 54.1-3442.8. Criminal liability; exceptions.**

366 No agent or employee of a pharmaceutical processor or cannabis dispensing facility shall be
367 prosecuted under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of
368 marijuana or for possession, manufacture, or distribution of cannabis ~~or~~ *products*, subject to any civil
369 penalty, denied any right or privilege, or subject to any disciplinary action by a professional licensing
370 board if such agent or employee (i) possessed or manufactured such marijuana for the purposes of
371 producing cannabis ~~or~~ *products* in accordance with the provisions of this article and Board regulations
372 or (ii) possessed, manufactured, or distributed such cannabis ~~or~~ *products that are consistent with*
373 *generally accepted cannabis industry standards* in accordance with the provisions of this article and
374 Board regulations.

375 **2. That the Board of Pharmacy shall establish testing standards for botanical cannabis and**
376 **botanical cannabis products consistent with generally accepted cannabis industry standards.**

377 **3. That the Board of Pharmacy shall promulgate regulations implementing the provisions of this**
378 **act including its enactment clauses. The Board's adoption of regulations shall be exempt from the**
379 **Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board shall**
380 **provide an opportunity for public comment on the regulations prior to adoption. The Board shall**
381 **complete work on such regulations in order that they will be implemented no later than**
382 **September 1, 2021.**

383 **4. That the Board of Pharmacy may assess and collect botanical cannabis regulatory fees from**
384 **each pharmaceutical processor in an amount sufficient to implement the first, second, and third**
385 **enactments of this act.**

386 **5. That the Board of Pharmacy's acquisition of a commercially available cannabis-specific software**
387 **product to implement the provisions of this act is exempt from the requirements of the Virginia**
388 **Public Procurement Act (§ 2.2-4300 et seq. of the Code of Virginia).**

Virginia.gov Agencies | Governor



General Notice

Comment period on pharmaceutical processor regulations

Date Posted: 5/6/2021

Expiration Date: 7/5/2021

Submitted to Registrar for publication: YES

[60 Day Comment Forum](#) is underway. Began on 5/6/2021 and will end on 7/5/2021

Notice of Public Comment Period

Board of Pharmacy

Regulations Governing Pharmaceutical Processors

In accordance with Chapters 205, 227, and 228 of the 2021 Acts of the Assembly, the Board of Pharmacy is providing an opportunity to comment on a draft of proposed regulations for pharmaceutical processors that will be considered for adoption as an exempt action.

The proposed regulations as drafted:

- Amend regulations as required by the 2021 legislation (those are highlighted in the attached document);
- Replace the references to “cannabis oil” with “cannabis products;” and
- Incorporate other amendments that are currently in effect as emergency regulations (those changes are shown with underlining or overstriking but are not highlighted).

https://www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm

The 2021 legislation requires posting of a notice 60 days in advance of submittals for public comment and also requires amended regulations to be effective by September 1, 2021. Therefore, the Board of Pharmacy is scheduled to meet on July 6, 2021 with the intent of submitting regulations to the Register of Regulations by July 14, 2021 for publication on August 2, 2021 with an effective date of September 1, 2021.

Although the Board will receive public comment from May 6, 2021 to July 5, 2021, commenters are **strongly encouraged** to submit comments by June 18, 2021 in order to have them included in the Board’s agenda package and adequately considered for the July 6th meeting.

Comments may be sent to: elaine.yeatts@dhp.virginia.gov

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Summary of Comments that May Warrant Regulatory Action

Regulation Section #	Commenter	Comment/Concern	Staff Response/Action Taken
	Dalitso/VMCC	Requests acknowledgement of statutory provisions for "designated caregiver facilities".	Allowance for designated caregiver facility staff to accept delivered products for patients is covered in the bill/Code. Unnecessary to replicate in regulation.
10	Dalitso/VMCC	Clarify definition of "batch"	Definition clarified
10	Dalitso	Request to add "reconciled monthly" to the definition of "Perpetual Inventory"	No change made; reconciliation "at least monthly" is included in 230 C.
10	Dalitso	Recommend adding "usable cannabis" to definition of "production"	Change made.
30 #4	Dalitso	Recommend acknowledging in regulation allowance for verbal or written authorization for botanical cannabis for minors if not captured on written certification.	Change made and added requirement for pharmacist to document
30 D	Dalitso/VMCC	Add language in regulation to acknowledge statutory allowance for "authentic electronic signature" on written certification.	Addressed in bill/Code; not necessary to repeat in regulation.
60 A 6	Dalitso/VMCC	Remove ability to deny issuance of registration based on prior conviction pertaining to controlled substances. Should not preclude medical treatment.	Policy decision. Allows the Board to deny if there is a flagrant violation. Has been removed from application. Cannabis is not a "controlled substance".
80 A	Dalitso	<ol style="list-style-type: none"> 1. Requests clarifications regarding transportation authority and delivery 2. Adult use bill/regulating transportation 	<ol style="list-style-type: none"> 1. Comment appears to be requesting added regulation regarding delivery requirements/responsibilities/protections. Regulations currently allow for a delivery agent. 2. The current requirement does not impede any legal possession of medical cannabis products.
80 B 2	Dalitso	Legality of cannabis and disposal requirements	These requirements address medical cannabis products, not adult use products. The current requirement does not impede legal possession of medical cannabis products under state law.
90 #4	Dalitso	Recommend adding allowance for 4 ounces botanical cannabis within 30 day period	Added
90 #10	Dalitso/VMCC	Request to remove ability to suspend or revoke based on any violation of federal or state law or regulation;	Policy decision (relates to 60 A 6 above)

Summary of Comments that May Warrant Regulatory Action

110 D	Dalitso/VMCC	Acknowledge statutory reference to "material owner"	Language changed to clarify criminal background check required of persons with 5% or greater ownership.
135 B 5	Dalitso/VMCC	Acknowledge statutory reference to "material owner"	Language changed to clarify criminal background check required of persons with 5% or greater ownership.
170 C	Dalitso/VMCC	Remove qualifications of responsible party; allow processor to determine who is and isn't qualified; Board does not appear to have authority to regulate qualifications	Counsel confirmed board does have authority to set qualifications; proposed qualifications are consistent with requirements for someone supervising an employ performing cultivation or extraction-related duties who has less than two years of experience (Lines 182-189, HB 1988)
190 A	Dalitso/VMCC	Remove "production or" because pharmacist to technician ratio doesn't apply to production areas with removal of pharmacists from those areas.	This should remain. If a processor chooses to have a pharmacy technician work in the production area, they must be under the supervision of a pharmacist.
190 B	Dalitso	Same as 190 A	Same as 190 A
215 A	Dalitso/VMCC	Advertisement regulations are too restrictive: vape shops advertising delta-8 THC and pharmacies advertising CBD with no restriction and enforcement. Requests removal of the prohibition to advertise through any means unless at least 85% of audience reasonably expected to be 18 years of age or older. Difficult to determine, keep up to date, and enforce.	In a review of other states, this ranged from 71% to 85% in states that have such a requirement.
215 B	Dalitso/VMCC	Request to add language regarding therapeutic or medical claims	Language added.
215 C 1	Dalitso/VMCC	Remove "health-related"	Removed
215 C 3	Dalitso	Typographical change	Change not made; appears correct as F.
215 C 4	Dalitso/VMCC	Language unclear. Requests clarification regarding intent. Can photos of products in ads be visible to public? Can processor/dispensary display cannabis products? Can products be visible to someone walking by dispensary through window?	Policy decision of the Board.
215 C 5	Dalitso/VMCC	Changes requested regarding promotional items, giveaways, coupons, branded and unbranded merchandise. Language offered on pg. 6 of VMCC comments.	Changes made.

Summary of Comments that May Warrant Regulatory Action

215 E (now F)	VMCC	Request for other items to be allowed on the <u>website</u> , e.g., educational materials, informational videos such as a virtual tour or how to use products, job listings, links to well-known medical cannabis research sites, etc.	Some new language added. Policy decision of the Board. Nothing prohibits the posting of how to become a patient, product pricing such as discounts and loyalty programs, in addition to job postings as this currently occurs.
215 F (now G)	Dalitso/VMCC	Requests allowance to communicate and engage the <u>public for educational purposes</u> , including dissemination of information, without it constituting advertising.	Line 138, HB 1988, is specific to practitioners and patients, not public. Policy decision to add general public, possibly with appropriate parameters relating to the rest of the advertising requirements. Are presentations okay, newspaper ads, handing out freebies – and how would this not constitute advertising?
215 G (now H)	Dalitso/VMCC	1. Request is in regard to the preexistence of a cannabis facility and subsequent location of a school, daycare, etc. 2. Request regarding corrective action; board to provide notice and 30 days to correct, then may fine processor \$1,000 for violation. 3. Request clarification on private playground	1. Guidance has already been issued on location of a facility in regard to this. 2. Outside the scope of this regulation. Removes board discretion on matter; 30 days for corrective action may be too long depending on circumstances. 3. The language does not specify playground equipment attached to a private residence-not the intent of the language.
215 J (now K)	Dalitso/VMCC	Requests ability to advertise at sporting events, on billboards, and any other advertisement that meets thresholds already established in proposed regulations and for purpose of making patients aware that a legal medical cannabis program exists.	Policy decision; Lines 287-288 of HB 1988 authorize board to restrict advertisements on public property, including public transit vehicles and facilities.
215 K (now L)	Dalitso/VMCC	Requests ability to advertise on public transit for purpose of making patients aware that a legal medical cannabis program exists.	Policy decision; Lines 287-288 of HB 1988 authorize board to restrict advertisements on public property, including public transit vehicles and facilities.
220 C	Dalitso/VMCC	Requested added language regarding employee access to align with the bill	Language added
220 D	Dalitso	Remove the testing requirements	Bill language states that the hemp based CBD products sold in a pharmaceutical processor must meet the testing standards for hemp oil purchased by the processor. Changed from the entire 280 to 280 D 2 & 3 which references testing.
240 D	Dalitso/VMCC	Concern that current language restricting access to keys and codes to responsible party, pharmacists, or	Clarified language that only pharmacists and supervisors of cultivation/production and authorized by responsible party may

Summary of Comments that May Warrant Regulatory Action

		supervisors of cultivation or production-related activities inadvertently limits employees from accessing their assigned work areas.	have access to keys and codes for safes, vaults, secured areas. Clarified that other designated employees may have ability to unlock secured area to perform duties only during hours of operation and may never have access to security system.
251 A	Daltso	<ol style="list-style-type: none"> 1. Recommends clarifications regarding wholesale distribution and testing prior 2. Packaging requirements for wholesale-removes the ability to wholesale between a processor and dispensary 3. Adds requirements for how products should be marked. 	<ol style="list-style-type: none"> 1. Changed the testing language as appropriate 2. Allowed in Code. 3. Added language to 251 C to address.
251 B	Daltso	Request to add language to allow for wholesale distribution of botanical cannabis between cannabis dispensing facilities.	Not addressed/allowed in the bill/Code.
285 C	Daltso	Requested additional language for registration of brand names	No changes made at this time; Exceeds the scope of the bill and this regulation
285 D	Daltso/VMCC	Request to acknowledge in regulation the statutory language that board shall register all cannabis products that meet testing, labeling, and packaging standards.	Unnecessary since already in Code.
		Daltso recommends certain characteristics be exempt from board's scope of review during product registration; prescribes process for product denial or delay.	No changes made.
290 B 2 h	Daltso	Recommends language regarding labeling requirement for potency	Addressed through changes
290 B 2 i	Daltso	Clarification for testing labeling requirements	Changed
290 C	Daltso	Recommends allowance for approval of labeling on a subsequent product if previous product approved. Indicates labeling deemed to satisfy requirements unless board notifies processor of cited deficiency	No changes made. Issue has not yet arisen. Also, imposes time restrictions on board staff which may not always be reasonable depending on workload, exponential growth of program, and limited staff.

Summary of Comments that May Warrant Regulatory Action

		within 15 days of receipt of request for product registrat		21
300 A	American Association for Laboratory Accreditation (A2LA)	Strongly support section 18VAC110-60-300 A. that requires ISO/IEC 17025 Accreditation through an ILAC signatory as required in section 18VAC110-60-300.	No change required.	
300 A 1	Dalitso	Comment to add requirement for the labs to affirm their independence	Policy decision on affirmation. Independent status requirement is already in the regulation.	
300 A 6	Dalitso	Comment to add requirement for labs to submit a security plan for board approval.	No changes made.	
300 B	American Association for Laboratory Accreditation (A2LA)	Clearly state that the sample collection of cannabis regulated under this rule, be collected by the accredited cannabis testing laboratory. This will ensure that the sample is collected appropriately and objectively, by an impartial sampling agent.	54.1-3442.6 states processor shall make sample available to lab. Unclear if this precludes recommendation for lab to collect sample, but lab required to establish minimum sample size for botanical cannabis.	
300 B	Dalitso/VMCC	Request to separate sample and testing processes for botanical cannabis from cannabis oil. Clarify testing requirements.	Changes made.	
300 B 1 (submitted version)	Dalitso	Comment to reduce minimum sample size of cannabis oil products down from current 0.5% of individual units	No change made. Sample size of 0.5% required in Code.	
300 B 2 (submitted version)	Dalitso	Language regarding not testing a harvest batch if being used for oil.	Not required as there is a standard for testing oil/processed products. It was never the intent to add a step here and this has been addressed by separating testing requirements	
300 B 3 (submitted version)	Dalitso	Language added regarding testing.	Language is not necessary.	
300 B 4 (submitted version)	Dalitso	Language added regarding the ability of a processor to request voluntary testing in a private agreement not known to the BoP.	No changes made.	
300 F (now G & H)	Dalitso/VMCC	1. Request to use different action levels for microbial testing requirements for botanical cannabis (used by	1. Changes made. 2. The product should be tested for all required tests to ensure no other issues have arisen, or no other problems have	

Summary of Comments that May Warrant Regulatory Action

		<p>MD, NV, MA, CT, and OH) and remove requirement to test for residual solvents.</p> <p>2. Request to retest only for tests that failed</p> <p>3. Comment to add heavy metals failure to the restriction on processing botanical into oil</p> <p>4. Addition of language to reflect back on Daitso's addition in subsection B4</p> <p>5. Comment to raise the water activity level to 0.7</p>	<p>occurred with the batch, nothing has been added since initial testing. It becomes a new batch when it goes through remediation.</p> <p>3. This would exceed what is written in Code.</p> <p>4. No change made; not reporting lab results to board could be problematic.</p> <p>5. While 0.7 should not allow anything to grow, it should actually be under 0.7. Washington, D.C, Washington State, Oregon, Maryland, and California all utilize 0.65. This appears to be the industry standard.</p> <p>Policy decision.</p>	22
300 G (now J)	Daitso/VMCC	<p>Request to allow for an expiration date of one year or less from date of packaging for botanical similar to MD, MA, NV, and PA.</p>	<p>Added language that expiration date must be set based on stability testing, but that stability testing not required if expiration date of 6 months or less assigned to cannabis product.</p>	
300 G (now J)	Daitso	<p>1. Clarification on testing requirements.</p> <p>2. Reference to new B4 (voluntary lab testing that's not reported board).</p>	<p>1. Change made.</p> <p>2. No change made; not reporting lab results to board could be problematic.</p>	
300 I (now K)	Daitso	<p>Reference to new B4 (voluntary lab testing that's not reported board).</p>	<p>No change made; not reporting lab results to board could be problematic.</p>	
321 A (Same as 220 D)	Daitso	<p>Removed the testing requirements</p>	<p>Bill language states that the hemp based CBD products sold in a pharmaceutical processor must meet the testing standards for hemp oil purchased by the processor. Changed from the entire 280 to 280 D 2 & 3 which references testing.</p>	
321 B	Daitso	<p>Addition of "potential and registered" patients, parents, etc.</p>	<p>Does not need to be added. "Potential" people are not allowed in the dispensary, only "registered" people.</p>	
330 A	Daitso	<p>Suggestion to remove "misbranded" due to a federal law definition</p>	<p>The term "misbranded" is also used in relation to pharmaceutical products.</p>	
330 A	Daitso	<p>Suggestion to use "usable cannabis" instead of green waste</p>	<p>Green waste is defined. No change necessary.</p>	

Summary of Comments that May Warrant Regulatory Action

330 A	Daltso	Language for resulting green waste and agricultural waste	Language added.
330 B	Daltso/VMCC	Requests removal of requirement for pharmacist and another employee to witness destruction/disposal of cannabis products under video surveillance. Recommends allowing two employee witnesses.	Policy decision of the Board.
330 B	Daltso	Added the term "destroying"	Language added



June 18, 2021

Caroline Juran
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233

Ms. Juran:

On behalf of the Virginia Medical Cannabis Coalition, please find our public comment regarding recommended amendments to the proposed “Regulations Governing Pharmaceutical Processors” as a result of legislation from the 2021 General Assembly Session.

We want to thank the Board of Pharmacy for all the work that has gone into establishing the medical cannabis program in Virginia. Medical cannabis is not new but is new to the Commonwealth, and we hope that these suggestions based on experiences in other states will help to move the program forward and increase patient access.

While we have included comments across several issues, we would like to draw specific attention to the section on testing. It is important to note that the testing standards for botanical and oil products require different tolerance levels; however, the proposed regulations appear to consider them the same. We hope the Board of Pharmacy will work with us to ensure proper testing limits and procedures for botanical cannabis products to ensure that this treatment option is accessible to Virginia’s registered patients as soon as the law permits.

Virginia’s pharmaceutical processors are ready and willing to serve as a resource in developing the medical cannabis program policies. Please let us know if you have any questions or need additional information. Thank you for your consideration.

Sincerely,

Joy A. Strand, MHA
VMCC Legislative Committee Chair
Executive Vice President, gLeaf

Ngiste Abebe
Vice President of Public Policy, Columbia Care

Jack Page
CEO, Dharma Pharmaceuticals

Sara Payne
Senior Corporate Counsel, Jushi Holdings



Below please find sections of the proposed regulations with suggested changes or amendments and the rationale behind these suggestions. The main sections included in these comments are:

1. 118VAC110-60-10. Definitions
2. 118VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations
3. 18VAC110-60-215. Advertising
4. 18VAC110-60-240. Security Requirements
5. 18VAC110-60-300. Laboratory requirements, testing

We have included the proposed regulation, our comments in gray, and our proposed amendments in red italic throughout.

At the end of the document please find a series of additional provisions that were amended during the 2021 General Assembly Session but do not have corresponding changes in these proposed regulations at this time.

18VAC110-60-10. Definitions.

"Batch" means a quantity of cannabis ~~oil~~ product from a harvest or production lot that is identified by a batch number or other unique identifier.

VMCC asks for a small amendment to the definition of batch for clarification. Without an edit, we believe this could be read that all cultivated cannabis constitutes a batch as harvested regardless of whether or not it is sold as flower or then processed into oil. This could potentially require double testing of oil products—both when we cut at the harvest stage, and when the processed product is ready for testing. As the process today does not require double testing and such a requirement would create a myriad of inefficiencies and barriers, we ask for the following change for clarity.

"Batch" means a quantity of cannabis ~~oil~~ product from a (i) *harvest of a botanical cannabis product* or (ii) a production lot if a cannabis oil product, that is identified by a batch number or other unique identifier.



18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations.

118VAC110-60-170(C)

C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application, shall have oversight of the cultivation and production areas, and shall possess:

1. A current, unrestricted license as a pharmacist issued by the board;

2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;

3. A certification recognized by the board; or

4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.

Our review of the statutory authority indicates that while the Board must establish a responsible party designation requirement, and may assign responsibilities of that responsible party within the statutory framework, the Board does not appear to have the authority to regulate the qualifications of the responsible party. The pharmaceutical processors are committed to designation of only qualified individuals, but the pharmaceutical processors are in the best position to determine who is and isn't qualified to serve as the pharmaceutical processor's responsible party. The proposed regulations may disqualify well-qualified employees currently serving in a leadership position within the pharmaceutical processor. Accordingly, the pharmaceutical processors request the following amendment.

C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application, shall have oversight of the cultivation and production areas, ~~and shall possess:~~

~~1. A current, unrestricted license as a pharmacist issued by the board;~~

~~2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;~~

~~3. A certification recognized by the board; or~~



~~4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.~~

18VAC110-60-215. Advertising.

We believe the proposed advertising regulations are overly restrictive and make it difficult for processors to make their legal and safe products known in a sea of unregulated, untested, and illegal products. Currently the only legal way to purchase medical cannabis in Virginia is via a licensed pharmaceutical processor and yet unregulated and unlicensed vape shops selling Delta-8 products are able to advertise in any way they would like with no restriction and no enforcement.

Additionally, pharmacies across Virginia regulated by the Board of Pharmacy are heavily advertising CBD products and making health claims for these products on their websites, in flyers sent to homes, and online and are subject to no Board of Pharmacy advertising prohibitions.

The processors are unable to properly educate the public on the safe products available to them when we are left with few (if any) avenues for advertising. VMCC respectfully asks the Board to re-evaluate the proposed advertising regulations to allow pharmaceutical processors ways to simply make the public aware that a safe and regulated medical cannabis industry exists in the Commonwealth.

18VAC110-60-215(A)

~~A. A pharmaceutical processor or cannabis dispensing facility shall not advertise (i) through any means unless at least 85 percent of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time outside of regular school hours for elementary and secondary schools.~~

While we understand that this mirrors proposed advertising laws for the retail marijuana program, in some states like Maryland, such language was proposed for its medical cannabis program but failed to become finalized. In particular the 85% threshold is difficult to determine, keep up to date, and enforce.

18VAC110-60-215(C)

~~C. Advertising shall not:~~



1. Be misleading, deceptive, false or contain any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;

The health and safety of medical cannabis products is of the utmost importance to VMCC and its member pharmaceutical processors. We would ask that specific details regarding therapeutic or medical claims be clarified in the regulations. VMCC suggests the following language as section B under the “advertising” section on health-related claims to make this very clear and that “health-related” be stricken from section C given this expanded provision.

B. All advertisement for cannabis products that make therapeutic or medical claims shall:

- 1. Be supported by clinical evidence or clinical data; and*
- 2. Include information on the most significant side effects or risks associated with the use of cannabis.*

18VAC110-60-215(C)(4)

C. Advertising shall not:

4. Display cannabis products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place; and

This language is unclear in its intention. Is this intended to be that a processor cannot include photos of cannabis products in advertisements visible to the public or is it that a processor cannot display cannabis products themselves? Or does this mean that someone walking by a dispensary shall not be able to view medical cannabis products through the window?

18VAC110-60-215(C)(5)

C. Advertising shall not:

5. Include promotional items such as giveaways, coupons, and distribution of branded or unbranded merchandise.

Subsection (c)(5) raises a number of concerns for VMCC and its member pharmaceutical processors.

1. What is the definition of a coupon? Coupon is not referenced in these regulations and typically would not apply to the medical cannabis industry.
2. Can a processor offer discounts to classes of patients and not run afoul of the meaning of a coupon? For example a standard discount for veterans or discounts for low income



patients. Medical cannabis is not covered by any insurance and is a 100% out-of-pocket cost for patients. As such, offering discounts is often the only way to offer a more affordable product price to certain patients.

3. Are processors permitted under these provisions to run specials or offer sales for reduced cost products? This is a standard industry practice that helps patients afford this medication, and putting short-dated products on sale is commonplace, efficient and cost-effective for maintaining market inventory.
4. What is the rationale behind the prohibition of distributing branded or unbranded merchandise? The use of branded and non-branded merchandise and promotional materials is a widely accepted practice in similar industries, including both pharmaceutical companies and pharmacies. Pharmaceutical processors are expressly prohibited from offering such items in the proposed regulations. There is no prohibition present for other similar industries in either state statute or regulation. We would suggest that this prohibition be lifted for pharmaceutical processors as long as such items are in compliance with 18VAC110-60-215. VMCC member pharmaceutical processors are not aware of such a blanket prohibition in any other medical cannabis program, and branded items are common practice in states with robust medical programs.

We respectfully ask that this subsection be revised to allow pharmaceutical processors to establish themselves in Virginia with their safe and tested products. We agree with the Board that free samples or free products should be prohibited. We are seeing free samples being given out across Virginia of often illegal and unsafe CBD products and think the Commonwealth should look at ways to also crack down on these entities. VMCC does not want the ability to follow suit but processors do need some flexibility in order to make the availability of safe products known in Virginia. VMCC proposes the following language based off of Illinois' medical program to limit promotional activities and giveaways but not completely hinder a pharmaceutical processor's ability to offer patients discounts or promotional items.

C. Advertising shall not:

5. ~~Include promotional items such as giveaways, coupons, and distribution of branded or unbranded merchandise.~~ *Encourage the sale of cannabis or cannabis products by giving away cannabis or cannabis products, by conducting games or competitions related to the consumption of cannabis or cannabis products, or by providing promotional materials or activities of a manner or type that would be appealing to children.*

18VAC110-60-215(E)

E. A pharmaceutical processor or cannabis dispensing facility may display the following information on their website or social media site:

1. Name and location of the processor or facility;



2. Contact information for the processor or facility;

3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor or facility.

The regulations around what “may” be displayed on the website of a pharmaceutical processor leave ambiguity around what a pharmaceutical processor can and cannot place on their website. The website is our primary method of education for patients about medical cannabis and our facilities. Based on this language can a processor post informational videos on their website such as a virtual tour or how to use a product or provide informational resources regarding specific products? Can a processor include job listings on their website or provide links to well-known medical cannabis research sites? Can a processor give information on how to become a patient?

With all of the illegal and unsafe products in the marketplace, VMCC members would like the ability to educate the public via their website to the fullest ability. The listing of such specific items seems to imply that nothing else can go on a website but it is essential that processors be able to provide more information to patients. An educated patient is an absolute must.

Our concern is that this list may be used by inspectors as an inclusive list and any additional information we place on our websites could create inspection deficiencies. As long as this is section not a prohibition on pharmaceutical processors putting additional educational and informative items on sites then we withdraw our concerns.

18VAC110-60-215(F)

F. Communication and engagement for educational purposes with *the public*, registered practitioners, and registered patients, parents, legal guardians and registered agents, including the dissemination of information permitted by 18VAC110-60-215 E and educational materials regarding the use of cannabis products available from the pharmaceutical processor or cannabis dispensing facility is allowed *shall not constitute advertising.*

Due to rampant misinformation on CBD and cannabis based products in the marketplace in Virginia, VMCC respectfully asks for the above blanket allowance for communications that educate the public, practitioners, and patients. As previously stated, the unfettered advertising of



illicit products can only be combatted if the pharmaceutical processors are allowed to educate the public, not just registered patients.

18VAC110-60-215(G)

G. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility.

VMCC seeks clarification on the Board's definition of a private playground. While we believe this might mean a playground for use of particular children such as in a private neighborhood, we want to ensure that this would not inadvertently capture all playground equipment at private residences.

Additionally, due to potential changes in business locations or errors made by the companies that place outdoor advertising, we would like the Board to consider the following subsection language similar to that proposed in the retail marijuana legislation to allow for corrective action of outdoor advertising should a pharmaceutical processor's sign be placed in the wrong location.

- 1. For violations of relating to distance and zoning restrictions on outdoor advertising, the Board shall give the advertiser written notice to take corrective action to either bring the advertisement into compliance with this section and Board regulations or to remove such advertisement. If corrective action is not taken within 30 days, the pharmaceutical processor will be fined \$1,000.*

18VAC110-60-215(J), (K)

J. A pharmaceutical processor or cannabis dispensing facility shall not advertise at any sporting event or use any billboard advertisements.

K. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location.

VMCC would ask the Board to consider allowing advertising via billboards and on public transit for the purposes of making patients aware that a legal medical cannabis program exists. Additionally, we would ask that the prohibition of sporting events be removed. If the sporting



event, billboard, or any other advertisement can meet the thresholds already established here in the proposed regulations, then we would ask that those advertisements be allowed. Currently, pharmacies, vape, and CBD shops are advertising CBD products all over the Commonwealth on billboards, in coupon packets sent to households, at sporting events, and anywhere you can think of. Completely prohibiting such advertising avenues of the pharmaceutical processors' legal products is only helping to bolster the prevalence of illegal products in the marketplace.

Billboards are currently allowed for medical cannabis, with specific restrictions, in states such as Arizona, California, Illinois, and Maryland. These billboards are tastefully done and must meet the requirements in the regulations already established. We agree with concerns around a billboard depicting someone smoking marijuana but such a depiction would be prohibited per the provisions included. A billboard with a processor logo, website, and address would serve to create awareness of the legal medical cannabis industry without negative imagery. We ask that such advertising be permitted in order to displace the illicit market and notify the public of the location of our facilities.

J. A pharmaceutical processor may use billboard advertisements or advertise at sporting events if such advertisements are meant to educate or notify the public of the contact information and location of a facility. Such advertising must adhere to the requirements of 18VAC110-60-215.

K. Cannabis product advertising may be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location if such advertisements are meant to educate or notify the public of the contact information and location of a facility. Such advertising must adhere to the requirements of 18VAC110-60-215.

18VAC110-60-240. Security requirements.

D. Access to keys or codes in areas of a pharmaceutical processor that designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor.

We interpret this new provision to restrict regular, non-supervisory employees from accessing their own work areas via keys or codes. Due to the wording that access to keys or codes “shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing.....or person supervising...” This appears to inadvertently limit our employees from accessing their own work areas unless a supervisor, pharmacist, or the responsible party admits them into the area. VMCC suggests the following language to mitigate



these concerns. As a secure facility, it is common practice to only grant access to a specific area of the processor when the employee has a need to access that area due to work duties.

Access to areas of a pharmaceutical processor that are designated for cultivation and production shall be restricted unless the responsible party, pharmacists practicing at the pharmaceutical processor, or persons supervising cultivation or production activities at the process, have authorized such personnel to be present in these areas.

18VAC110-60-300. Laboratory requirements; testing.

18VAC110-60-300(B)

B. After processing and before dispensing ~~the~~ any cannabis ~~oil~~ product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, ~~and~~ pesticide chemical residue, and, for botanical cannabis, the water activity and moisture content, and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The same must be representative of the entire batch to include selection from various points in the batch container and be of sufficient sample size to allow for analysis of all required tests.

By including both botanical cannabis and extract/concentrate products together in this section it is unclear what needs to be done for the sampling and testing process of the different products. Botanical cannabis that is going directly to become an oil product should function for sampling and testing just as it does today—be tested after processing is complete. Botanical cannabis need not be tested for residual solvents since no processing takes place, no solvents are introduced to the botanical product, and additionally, the legislation regarding botanical cannabis very specifically outlined what botanical cannabis shall be tested for, and residual solvents are not included in this explicit list.



VMCC submits that clarification is possible by separating the two sample and testing processes into two distinct subsections as outlined below.

B. Cannabis oil products and botanical cannabis products will be tested according to the following:

1. From each homogenized batch of cannabis oil product, a pharmaceutical processor shall make a sample available for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue, and (ii) conduct an active ingredient analysis and terpene profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

2. From each harvest batch of botanical cannabis product, a pharmaceutical processor shall make a sample available for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, water activity and moisture content. In determining the minimum sample size for testing from each harvest batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The sample must be representative of the entire batch to include selection from various points in the batch and be of sufficient sample size to allow for analysis of all required tests. Testing of a harvest batch of botanical cannabis to be processed into cannabis oil is not required. The processed cannabis oil will be tested according to subsection 1 above.

3. All cannabis products will be tested in accordance with the requirements of this subsection.

18VAC110-60-300(F)



F. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent. and an active ingredient analysis and terpenes profile shall be conducted. A batch of botanical cannabis that is tested in the same manner, with the addition of water activity and moisture content, may be remediated by the pharmaceutical processor if it does not pass testing requirements. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all testing standards set forth in this section.

Due to different testing standards and remediation procedures for cannabis oil products and botanical cannabis products, VMCC asks that this section be streamlined to the following suggested language. The current language around botanical cannabis testing leaves some ambiguity as residual solvent testing is not required, but testing for water activity and moisture content is required.

F. Remediation of cannabis products.

- 1. If a sample of a cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the batch may be remediated with further processing and submitted for retesting.*
- 2. If a sample of botanical cannabis fails testing requirements for microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity, and moisture content, the processor may remediate the batch and submit a sample for retesting. If the batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related*



to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all applicable testing standards.

18VAC110-60-300(F)(1)

1. For purposes of the microbiological test:
 - (a) a cannabis *oil product* sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.
 - (b) *Botanical cannabis shall be deemed to have passed if it satisfies the action limits of 10,000 CFU/g of total yeast and molds and 100,000 CFU/g of total aerobic bacteria.*

This section in proposed regulations creates a significant hurdle for botanical cannabis. The listed categories in Section 1111 of the United States Pharmacopeia are for marijuana-infused products, and the microbial limits do not correlate to botanical products. According to the table in the United States Pharmacopeia, permitted microbes would only be 1,000 CFUs. 1,000 CFUs as a threshold would be difficult to reliably hit without needing to use remediation techniques for each and every batch. Most functioning markets for medical cannabis have a higher threshold limit based on the correct reading of the full text of the American Herbal Pharmacopoeia Monograph pertaining to orally consumed botanical products, resulting in action limits of 10,000 CFUs total Yeast and Molds and 100,000 CFUs total aerobic microbes per gram. This industry standard has been adopted in Maryland, Nevada, Massachusetts, Connecticut, and Ohio.

Below please find a chart of other states and their microbial limits.

MICROBIOLOGY	Units (CFU/g)					
	State	MD	NV	MA	CT	OH
Total Yeast and Mold		10,000	10,000	10,000	10,000	10,000
Total Aerobic Bacteria		100,000	100,000	100,000	100,000	100,000
<i>STEC E. coli</i>		100	0		0	1
Salmonella spp.		0	0		0	1
Bile Tolerant Gram Negative Bacteria			1,000	1,000	100	1,000
Total Coliforms			1,000	1,000		1,000

Because the same microbiological testing limits cannot be utilized for oil products and botanical products, we respectfully ask that Virginia follow other state medical cannabis programs and established industry standards by setting specific microbial limits detailed above.



18VAC110-60-300(G)

G. If a sample of cannabis oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, and for botanical cannabis, also the water activity and moisture content test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products, except stability testing shall not be required for cannabis oil products if the pharmaceutical processor assigns an expiration date of six months or less from the date of packaging. *Botanical cannabis products shall have an expiration date of one year or less from the date of packaging.*

As stability testing does not apply to botanical cannabis in the same way it does oil products, VMCC suggests setting forth an expiration date of one year for botanical cannabis products. One year is the standard expiration for flower in the medical cannabis industry. For example, Maryland, Massachusetts, Nevada, and Pennsylvania all use one year from the lab's certificate of analysis. Following the Board's original proposal for cannabis oil products, the VMCC recommends oil products have an expiration date of 6 months (previously approved by the Board), and botanical cannabis products have an expiration date of 1 year, both based on the date of packaging.

OTHER PROVISIONS:

With the legislation passed during the 2021 Session, there are a number of provisions in the regulations that present discrepancies with the statutory changes. While we understand that the Code trumps the regulations, we want to highlight these differences as they can at times create issues at inspection of our facilities. We request the addition of clarifying language in the regulations to match the statute to eliminate confusion.

- 18VAC110-60-30(B)(4):
 - Stipulates that the written certification be specific for botanical cannabis for a minor patient. The statute also states "if not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing." We would ask that the proposed regulations incorporate this verbal allowance.



- 18VAC110-60-30(D):
 - Through HB1988 the Code will now allow for an “authentic electronic signature.” We would ask that the proposed regulations be amended to allow an “authentic electronic signature” to avoid current issues around wet signatures being required of practitioners.
- 18VAC110-60-60(A)(6):
 - Allows the Board to deny a patient registration for a prior conviction pertaining to controlled substances. VMCC is unsure that it is legal to ask about such convictions with reference to marijuana and believes questions to this effect have already been removed from the application. Additionally, should someone and their doctor decide that medical cannabis is appropriate medicine, a prior conviction for a drug should not preclude them from such medical treatment. We respectfully ask for (6) of this section to be removed.
- 18VAC110-60-90(10):
 - Allows the Board to revoke or suspend patient registrations if a registrant violates any federal or state law or regulation. With the Commonwealth’s legalization of marijuana, we believe there may be a conflict here. Since marijuana is federally illegal, theoretically the use of marijuana may violate federal law and thus put any patient at risk of losing their registration. Additionally, does this mean that a traffic violation or unrelated misdemeanor criminal offense could put a patient’s registration in jeopardy? VMCC respectfully asks for (10) of this section to be removed due to ambiguities in the law.
- 18VAC110-60-110(D) and 18VAC110-60-135(5):
 - HB1988 changed criminal background check requirements to be for “material owners” and clarifies that criminal background checks can be conducted by any services sufficient to disclose state and federal crimes. We believe 18VAC110-60-110(D) should be amended to remove the prohibition of ownership if it is not “material ownership.” Additionally, 18VAC110-60-135(5) should be amended to specify an “applicant’s material owners” to be consistent with the Code.
- 18VAC110-60-190:
 - Remove “production or” from section A because the pharmacy technician ratio does not apply to production areas with the removal of the pharmacist from those areas. The ratio should now just apply to the dispensing areas.
- 18VAC110-60-220(C):
 - Insert “and production” on those areas in which the responsible party may authorize certain employee access when the dispensary is closed and a pharmacist is not on duty.
- 18VAC110-60-285:
 - In conjunction with the provision of SB1333, add section D, “The Board shall register all cannabis products that meet testing, labeling, and packaging standards.”
- 18VAC110-60-330:
 - The proposed regulations around disposal of cannabis products still require the witnessing of destruction and disposal by a pharmacist and at least one other employee. VMCC once again asks that this requirement for a pharmacist be reconsidered and allow waste disposal to take place with two employee witnesses as is standard industry practice. Green waste disposal is taking place each and every day at these facilities and requiring a pharmacist to watch this disposal means they cannot be working with patients in the dispensary.
- Designated caregiver facilities:



- The proposed regulations make no mention of the new category of “designated caregiver facilities” for the purposes of residents in certain care settings such as assisted living facilities. Since these residents will no longer be required to utilize a specific registered agent, we are concerned that the silence on designated caregiver facilities in the regulations may result in confusion with the registered agent process.

MACAULAY
& JAMERSON, P.C.

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June 21, 2021

VIA ELECTRONIC MAIL

Department of Health Professions
Attn: Elaine Yeatts, Agency Regulatory Coordinator
Department of Health Professions
9960 Mayland Drive
Henrico, VA 23233

**RE: Dalitso, LLC
Public Comment re: Pharmaceutical Processor Exempt Regulations**

Dear Ms. Yeatts:

Macaulay & Jamerson, P.C. represents Dalitso LLC (“Dalitso”) and its parent, Jushi Inc. On behalf of Dalitso, please find enclosed a proposed redline of changes to the draft Regulations Governing Pharmaceutical Processors.

Additionally, please note that Dalitso associates its position with the changes separately proposed by the Virginia Medical Cannabis Coalition (“VMCC”). A copy of VMCC’s proposed changes is attached here as well for reference. Where Dalitso has additional proposed changes or seeks to provide further context, those comments are incorporated into the attached redline.

Thank you for your consideration of Dalitso’s redline and VMCC’s requested changes.

Please feel free to contact me at 804.467.0307 should you have any questions.

Sincerely,



Hunter W. Jamerson
Counsel to Dalitso, LLC

cc: Caroline Juran, Executive Director
Annette Kelley, Deputy Executive Director
Megha Trivedi, Pharm.D., Dalitso, LLC
Sara Payne, Esq., Jushi Inc.

Board Of Pharmacy

Exempt action - 2021 legislation

Chapter 60

Regulations Governing Pharmaceutical Processors

Part I

General Provisions

Commented [HJ1]: As drafted, the regulations do not mention designated caregiver facilities. Given the statutory changes in HB 1988 which set forth that residents of designated caregiver facilities will no longer be required to utilize a specific registered agent, omission of designated caregiver facilities may result in confusion.

18VAC110-60-10. Definitions.

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"90-day supply" means the amount of cannabis oil products reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation, of visual, oral, or written communication, through any means, to directly induce any person to patronize a particular pharmaceutical processor or cannabis dispensing facility, or to purchase particular approved cannabis products. Advertising includes marketing.

"Batch" means a quantity of cannabis oil product from a (i) harvest if a botanical cannabis product, or (ii) a production lot if a cannabis oil product, that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabis oil products for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Dispensing error" means one or more of the following was discovered after the final verification by the pharmacist, regardless of whether the patient received the oil product:

1. Variation from the intended oil product to be dispensed, including:
 - a. Incorrect oil product;
 - b. Incorrect oil product strength;
 - c. Incorrect dosage form;
 - d. Incorrect patient; or
 - e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
 - a. Known therapeutic duplication;
 - b. Known drug-disease contraindications;
 - c. Known drug-drug interactions;
 - d. Incorrect drug dosage or duration of drug treatment;
 - e. Known drug-allergy interactions;
 - f. A clinically significant, avoidable delay in therapy; or
 - g. Any other significant, actual, or potential problem with a patient's drug therapy.
3. Delivery of an oil a cannabis product to the incorrect patient.

4. An act or omission relating to the dispensing of cannabis oil product that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis oil product is sold to a registered patient, parent, or legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

"On duty" means that a pharmacist, the responsible party, or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"Perpetual inventory" means an ongoing system, reconciled monthly, for recording quantities of cannabis oil received, dispensed, or otherwise distributed by a cannabis dispensing facility.

"PIC" means the pharmacist-in-charge designated on the pharmaceutical processor or cannabis dispensing facility application who shall have oversight of the processor's dispensing area or cannabis dispensing facility.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana for the creation of usable

cannabis, botanical cannabis, or a cannabis product derived thereof, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by a combination of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Qualifying patient" means a Virginia resident who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabis oil products for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis oil products to such patient.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, or legal guardian, or registered agent.

Commented [HJ2]: Can this be developed as an electronic document?

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Responsible party" means the person designated on the pharmaceutical processor application who shall have oversight of the cultivation and production areas of the pharmaceutical processor.

Commented [HJ3]: Will this result in an additional permit being issued?

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

Room or Phase	Temperature	Humidity
Mother room	65 - 75° 85° F	50% - 60% 75%
Nursery phase	74 65 - 85° F	65% 50% - 75%

Vegetation phase	74 65 - 85° F	55% 50% - 65% 75%
Flower/harvest phase	74 65 - 85° F	55% 40% - 60% 75%
Drying/extraction rooms	< 75° F	55% 40% - 60% 75%

"Temporarily resides" means a person that does not maintain a principle place of residence within Virginia but resides in Virginia on a temporary basis as evidenced by documentation substantiating such temporary residence.

Part II

Requirements for Practitioners and Patients

18VAC110-60-30. Requirements for practitioner issuing a certification.

A. Prior to issuing a certification for cannabis oil products for any diagnosed condition or disease, the practitioner shall meet the requirements of § 54.1-3408.3 of the Code of Virginia, shall submit an application and fee as prescribed in 18VAC110-60-20, and shall be registered with the board.

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition;
2. Diagnose the patient;
3. Be of the opinion that the potential benefits of cannabis oil products would likely outweigh the health risks of such use to the qualifying patient;
4. Authorize on the written certification the use of botanical cannabis for a minor patient if the practitioner determines such use is consistent with the standard of care to dispense botanical cannabis to a minor. If not specifically included on the initial written certification,

authorization for botanical cannabis may be communicated verbally or in writing by the practitioner to the pharmacist at the time of dispensing.

4- 5. Explain proper administration and the potential risks and benefits of the cannabis oil products to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

5- 6. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabis oil products for treating the diagnosed condition or disease;

6- 7. Comply with generally accepted standards of medical practice, except to the extent such standards would counsel against certifying a qualifying patient for cannabis oil products;

7- 8. Maintain medical records in accordance with 18VAC85-20-26 for all patients for whom the practitioner has issued a certification; and

8- 9. Access or direct the practitioner's delegate to access the Virginia Prescription Monitoring Program of the Department of Health Professions for the purpose of determining which, if any, covered substances have been dispensed to the patient.

C. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation, which may include the use of telemedicine, provided that the use of telemedicine:

1. Includes the delivery of patient care through real-time interactive audio-visual technology;

2. Conforms to the standard of care expected for in-person care; and

3. Transmits information in a manner that protects patient confidentiality.

Such telemedicine use shall be consistent with federal requirements for the prescribing of Schedules II through V controlled substances.

D. A practitioner shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a certification. Employees under the direct supervision of the practitioner may assist with preparing a certification, so long as the final certification is approved and signed, manually or by authentic electronic signature, by the practitioner before it is issued to the patient.

E. The practitioner shall provide instructions for the use of cannabis oil products to the patient, parent, or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

~~F. A practitioner shall not issue certifications for cannabis oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.~~

G. Upon request, a practitioner shall make a copy of medical records available to an agent of the Board of Medicine or Board of Pharmacy for the purpose of enabling the board to ensure compliance with the law and regulations or to investigate a possible violation.

18VAC110-60-40. Prohibited practices for practitioners.

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis oil products;

2. Offer a discount or any other thing of value to a qualifying patient, parent, or guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis oil product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil ~~is~~ products are dispensed or produced; or

4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor, a cannabis dispensing facility, or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabis oil products, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabis oil product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabis oil other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. Registration of a patient, parent, or legal guardian or registered agent.

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;
2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt or proof of temporary residency, if applicable, such as a current academic identification card from a Virginia institution of higher learning, rental agreement, utility bill, or attestation on a form prescribed by the board that contains information sufficient to document temporary residency in Virginia;
3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;
4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;
5. Payment of the appropriate fees; and
6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

Commented [HJ4]: Who may attest? Is there a standardized form? An attestation from the practitioner should be per se sufficient.

B. A patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis products on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, birthdate, and registration number of each registered patient for whom the individual intends to act as a registered agent;
2. Proof of identity in the form of a copy of a government-issued identification card;
3. Payment of the applicable fee; and

Commented [HJ5]: This limitation will be problematic for patients who are institutionalized or homebound, such as those patients who are in designated caregiver facilities. Note that designated caregiver facilities are omitted from the regulatory draft.

4. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

~~B. C.~~ A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

~~C. D.~~ Patients, parents, and legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabis ~~or~~ products.

18VAC110-60-60. Denial of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent application.

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;
2. Does not provide acceptable proof of identity, residency or temporary residency, or age of the patient to the board;
3. Provides false, misleading, or incorrect information to the board;
4. Has had a qualifying registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent denied, suspended, or revoked by the board in the previous six months;
or
5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabis ~~or~~ products; ~~or~~
- ~~6. Has a prior conviction of a violation of any law pertaining to controlled substances.~~

B. If the board denies an application or renewal of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent applicant, the board shall provide the applicant with notice of the

grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-80. Proper storage and disposal of ~~cannabidiol oil or THC-A oil~~ cannabis products by patients, parents, or legal guardians, or registered agents.

A. A registered patient, parent, or legal guardian, or registered agent shall exercise reasonable caution to transport and store cannabis oil products in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, or legal guardian, or registered agent shall dispose of all usable cannabis oil products in possession of the registered patient, parent, or legal guardian's ~~possession~~ guardian, or registered agent no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabis oil products. A registered patient, parent, or legal guardian, or registered agent shall complete such disposal by one of the following methods:

1. By removing the oil product from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.
2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, or legal guardian, or registered agent registration.

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, or legal guardian, or registered agent) under the following circumstances:

Commented [HJ6]: Processors and PICs need clarification RE: responsibility and regulatory authority for delivery and transport.

Further, this section contemplates transport but does not set forth any protections for those transporting properly or rules for what BOP would consider proper transport.

Passage of the adult use bill seems incongruent with continued regulation of transport by patients and agents as Virginians may possess up to a 1oz of dry weight cannabis under VA law beginning on July 1 and be subject to only a violation for a quantity between more than 1 oz and 1 lb.

Commented [HJ7]: The Board should consider revising this entire section to reflect the reality of legal possession beginning on July 1. When read in the context of legal possession, these provisions seem aggressive toward patients and risk treating patients like they are committing criminal acts instead of legally participating in a legal program. The unfortunate result of this culture is that many Virginians are driven to, or continue to participate in, the illicit cannabis market where they have no medical supervision and no information about the content and safety of the cannabis they are using to self-medicate.

Because possession will be legal by the time these regulations become effective, the Board should give serious consideration to the policy and public health, safety and welfare concerns when comparing the level of difficulty regulations create for patients to participate in the medical cannabis program so they can access safe and legal medicinal cannabis products vs procuring cannabis from the illicit market to self-medicate.

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;
2. The ~~patient, parent, or legal guardian~~ registrant provided false, misleading, or incorrect information to the board;
3. The ~~patient, parent, or legal guardian~~ registrant is no longer a resident of Virginia or is no longer temporarily residing in Virginia;
4. The ~~patient, parent, or legal guardian~~ registrant obtained more than a 90-day supply of cannabis oil products in a 90-day period or more than a 4 ounces of botanical cannabis within a 30 day period;
5. The ~~patient, parent, or legal guardian~~ registrant provided or sold cannabis oil products to any person, including another ~~registered patient, parent, or legal guardian~~ registrant;
6. The ~~patient, parent, or legal guardian~~ registrant permitted another person to use the registration of the ~~patient, parent, or legal guardian~~ registrant, except as required for a registered agent to act on behalf of a patient;
7. The ~~patient, parent, or legal guardian~~ registrant tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the ~~patient, parent, or legal guardian~~ registrant;
8. The registration of the ~~patient, parent, or legal guardian~~ registrant was lost, stolen, or destroyed, and the ~~patient, parent, or legal guardian~~ registrant failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed; or

9. The ~~patient, parent, or legal guardian~~ registrant failed to notify the board of a change in registration information or notified the board of such change more than ~~14~~ 15 days after the change;

10. ~~The patient, parent, or legal guardian~~ registrant ~~violated any federal or state law or regulation;~~

Part III

Application and Approval Process for Pharmaceutical Processors and Cannabis Dispensing Facilities

18VAC110-60-110. Application process for pharmaceutical processor permits.

A. The application process for permits shall occur in three stages: submission of initial application, award of conditional approval, and grant of a pharmaceutical processor permit.

B. Submission of initial application.

1. A pharmaceutical processor permit applicant shall submit the required application fee and form with the following information and documentation:

- a. The name and address of the applicant and the applicant's owners;
- b. The location within the health service area established by the State Board of Health for the pharmaceutical processor that is to be operated under such permit;
- c. Detailed information regarding the applicant's financial position indicating all assets, liabilities, income, and net worth to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis oil products pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;

d. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis ~~oil~~ products;

e. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of a permit;

f. Information necessary for the board to conduct a criminal background check on the applicant;

g. Information about any previous or current involvement in the medical cannabis ~~oil~~ industry;

h. Whether the applicant has ever applied for a permit or registration related to medical cannabis ~~oil~~ in any state and, if so, the status of that application, permit, or registration, to include any disciplinary action taken by any state on the permit, the registration, or an associated license;

i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabis ~~oil~~ products;

j. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;

k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the Cannabis plants and ~~oil~~ products; (iii) the location of all areas that may contain Cannabis plants or cannabis ~~oil~~ products; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress;

l. Documents related to any compassionate need program the pharmaceutical processor intends to offer;

m. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabis oil products and to safely dispense such products; and

n. Such other documents and information required by the board to determine the applicant's suitability for permitting or to protect public health and safety.

2. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the permit selection process.

3. The board shall conduct criminal background checks on applicants and may verify information contained in each application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.

C. In the event the board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in a health service area, the board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

D. No person who has been convicted of a felony ~~or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 of~~ under the Code of Virginia or another jurisdiction within the last five years shall ~~have any form of ownership~~ be a material owner, be employed by, or act as an agent of a pharmaceutical processor.

18VAC110-60-135. Application for and granting of a permit for a cannabis dispensing facility.

A. Pursuant to § 54.1-3442.6 of the Code of Virginia, the board may issue up to five cannabis dispensing facility permits for each health service area. A permit may be issued to a facility that is owned, at least in part, by the pharmaceutical processor located in that health service area for the dispensing of cannabis products that has been cultivated and produced on the premises of a pharmaceutical processor. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for each cannabis dispensing facility permit shall be submitted to the board, along with the following information and documentation:

1. The name and address of the facility, which shall not be within 1,000 feet of a school or daycare;
2. The name and address of the facility's owners with 5% or greater ownership;
3. Name and signature of pharmacist-in-charge practicing at the facility;
4. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis products; and
5. Information necessary for the board to conduct a criminal background check on the applicant's material owners.

C. Prior to issuing the permit, an inspection of the facility shall be performed by an agent of the board. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

D. A cannabis dispensing facility shall comply with all state and local laws and ordinances.

E. A cannabis dispensing facility permit shall not be issued to any person to operate from a private dwelling or residence.

F. No person who has been convicted of a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a cannabis dispensing facility.

G. If the cannabis dispensing facility is not operational within 90 days from the date the permit is issued, the board shall rescind the permit unless an extension is granted for good cause shown.

H. A cannabis dispensing facility shall be deemed to have commenced operation if it is in receipt of cannabis products from a pharmaceutical processor.

I. Once the facility is in possession of cannabis products, a pharmacist shall be on site at all times during the declared hours of operation.

Part IV

Requirements for Pharmaceutical Processor Personnel

18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations.

A. A pharmacist with a current, unrestricted license issued by the board practicing at the location of the address on the pharmaceutical processor or cannabis dispensing facility application shall be in full and actual charge of the dispensing area of a pharmaceutical processor or of a cannabis dispensing facility and shall serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the dispensing area of the pharmaceutical processor or of a cannabis dispensing facility at all times during its hours of operation ~~or whenever the processor is being accessed~~

~~C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application and, shall have oversight of the cultivation and production areas, and shall possess:~~

~~1. A current, unrestricted license as a pharmacist issued by the board;~~

~~2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;~~

~~3. A certification recognized by the board; or~~

~~4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.~~

G. ~~D.~~ A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia ~~and who has had at least two years of experience practicing as a pharmacy technician~~ may perform the following duties under supervision of a pharmacist:

1. The entry of drug dispensing information and drug history into a data system or other recordkeeping system;
2. The preparation of labels for dispensing the oil cannabis product or patient information;
3. The removal of the oil cannabis product to be dispensed from inventory;
4. The measuring of the oil cannabis product to be dispensed;
5. The packaging and labeling of the oil cannabis product to be dispensed and the repackaging thereof;
6. The stocking or loading of devices used in the dispensing process;
7. The selling of the oil cannabis product to the registered patient, parent, or legal guardian or registered agent; and

8. The performance of any other task restricted to pharmacy technicians by the board's regulations.

~~D. E.~~ A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, and extraction as authorized by the pharmaceutical processor, and duties associated with the dispensing of the oils products as authorized by the PIC or as otherwise authorized in law.

~~E.~~ A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.

~~F.~~ A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabis oil as authorized by the PIC.

~~G.~~ A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, and cannabis oil and shall ensure quality of the dispensed oils. Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC shall ensure security.

F. A pharmaceutical processor may employ individuals with less than two years of experience to perform cultivation-related duties under the supervision of an individual who has received a

degree in a field related to the cultivation of plants or a certification recognized by the board or who has at least two years of experience cultivating plants.

G. A pharmaceutical processor may employ individuals with less than two years of experience to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

H. ~~Except for certain employee access to secured areas designated for cultivation and authorized by the PIC pursuant § 54.1-3442.6 of the Code of Virginia, at~~ At no time shall the dispensing area of a pharmaceutical processor operate or be accessed without a pharmacist on duty. At no time shall the cultivation and production area operate or be accessed without an employee on duty who satisfies the requirements for providing direct supervision for the activities in the respective areas.

I. No person shall be employed by or serve as an agent of a pharmaceutical processor or cannabis dispensing facility without being at least 18 years of age.

J. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor or cannabis dispensing facility unless such license or registration has been reinstated and is current and unrestricted.

18VAC110-60-190. Pharmacy technicians; ratio; supervision and responsibility.

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor or a cannabis dispensing facility designated for ~~production or~~ dispensing shall not exceed ~~four~~ six pharmacy technicians to one pharmacist.

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabis or products resulting from the actions of a pharmacy technician shall constitute grounds

for action against the license of the pharmacist and the registration of the pharmacy technician.

As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabis oil product ~~production or~~ dispensing functions; and
2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian, or registered agent regarding (i) cannabis oil products or other drugs either before or after cannabis oil ~~has~~ products have been dispensed or (ii) any medical information contained in a patient medication record;
2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabis oil product or any other drug the patient may be taking;
3. Interpret the patient's clinical data or provide medical advice;
4. Determine whether a different formulation of cannabis oil product should be substituted for the cannabis oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or
5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

18VAC110-60-195. Responsibilities of the responsible party.

A. A person may only serve as the responsible party for one pharmaceutical processor at any one time. The responsible party shall be employed full-time in a managerial position at the location

of the processor and shall be actively engaged in daily operations of the processor during normal hours of operation.

B. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the pharmaceutical processor.

C. The responsible party shall ensure compliance with all security measures to protect the Cannabis within the cultivation and production areas from diversion at all times and ensure that cultivation and production is performed in a safe and compliant manner, free of adulteration and misbranding.

D. The responsible party shall be responsible for ensuring that:

1. All employees practicing in the cultivation and production areas are properly trained;
2. All record retention requirements are met;
3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and the cannabis products within the cultivation and production area are met; and
4. Any other required filings or notifications regarding the cultivation and production areas are made on behalf of the processor as set forth in regulation.

E. When the responsible party ceases practice at a pharmaceutical processor or no longer wishes to be designated as the responsible party, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the responsible party.

F. The outgoing responsible party shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, or cannabis products on hand in the cultivation and production areas on the date he ceases to be the responsible party, unless the

Commented [HJ8]: Logistically will permits be re-issued with the name of the responsible individual on them?

owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A responsible party who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the responsible party. If the responsible party knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the responsible party that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new responsible party.

H. An application for a permit designating the new responsible party shall be filed with the required fee within 14 days of the original date of resignation or termination of the responsible party on a form provided by the board. It shall be unlawful for a pharmaceutical processor to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

Part V

Operation of a Pharmaceutical Processor

18VAC110-60-215. Advertising.

A. A pharmaceutical processor or cannabis dispensing facility shall not intentionally advertise (i) through any means unless at least 85 percent of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time outside of regular school hours for elementary and secondary schools.

B. Advertising must accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility responsible for its content and include a statement that cannabis products are

for use by registered patients only. All advertisement for cannabis products that make therapeutic or medical claims shall:

1. Be supported by evidence-based clinical documentation; and

2. Include information on the most significant side effects or risks associated with the use of cannabis.

C. Advertising shall not:

1. Be misleading, deceptive, false or contain any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;

2. Contain a statement, design, illustration, picture, or representation that:

a. Encourages or represents the recreational use of cannabis;

b. Targets or is attractive to persons younger than 18 years of age, including a cartoon character, a mascot, or any other depiction or image that is commonly used to market products to minors;

c. Displays the use of cannabis, including the consumption, smoking, or vaping of cannabis;

d. Encourages or promotes cannabis for use as an intoxicant; or

e. Is obscene or indecent.

3. Display cannabis or cannabis product pricing except as allowed in 18VAC110-60-215 FE.

4. Display cannabis products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place. Advertising shall not depict the use

Commented [HJ9]: The draft regulation is unclear and would not be possible to implement. We propose this alternative to accomplish what we understand to be the intent of the regulation.

of cannabis or cannabis products where the advertisement is visible to members of the public in a physical public setting; and

~~5. Include promotional items such as giveaways, coupons, and distribution of branded or unbranded merchandise. Encourage the sale of cannabis or cannabis products by giving away cannabis or cannabis products, by conducting games or competitions related to the consumption of cannabis or cannabis products, or by providing promotional materials or activities of a manner or type that would be appealing to children.~~

C. A pharmaceutical processor or cannabis dispensing facility may list their business in public phone books, business directories, search engines, or other places where it is reasonable for a business to maintain an informational presence of its existence, and a description of the nature of the business but shall not engage in the use of pop-up digital advertisements.

D. Any website or social media site owned, managed, or operated by a pharmaceutical processor or cannabis dispensing facility shall employ a neutral age-screening mechanism that verifies that the user is at least 18 years of age, including by using an age-gate, age-screen, or age verification mechanism.

E. A pharmaceutical processor or cannabis dispensing facility may display, but is not limited to, the following information on their website or social media site:

1. Name and location of the processor or facility;
2. Contact information for the processor or facility;
3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;
4. Laboratory results;
5. Product information and pricing; and

Commented [HJ10]: We agree with the Board that free samples or free products must be prohibited. We are seeing free samples being given out across Virginia by pharmacies and vape shops selling often illegal and unsafe CBD products and think the Commonwealth must evaluate patient and public health risk associated with this conduct and use existing laws and regulations to pursue enforcement. However, patient education is critical and VMCC therefore advocates for flexibility to discuss the program, its requirements, related processes and cannabinoid-based medicines to interested members of the public 18 years of age and older.

Commented [HJ11]: Processors must have some degree of pricing flexibility to implement equity and need-based programs to support patients who could not otherwise afford their medicine. This is a standard industry practice and is instrumental to improving access, particularly to veterans, low-income patients, and patients of color who demonstrably participate at disproportionately low levels as compared to their non-minority counterparts.

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6. Directions to the processor or facility.

F. Communication and engagement for educational purposes with the public, registered practitioners and registered patients, parents, legal guardians and registered agents, including the dissemination of information permitted by 18VAC110-60-215 E and educational materials regarding the use of cannabis products available from the pharmaceutical processor or cannabis dispensing facility ~~is allowed~~ shall not constitute advertising.

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G. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility, to the extent the facilities described in (i) – (iii) existed and were operational for the use described prior to the original issuance of a conditional pharmaceutical processor or cannabis dispensing facility permit.

Commented [HJ12]: Due to the breadth of the language of the proposed rule, siting a facility described in the proposed regulation could materially impact a processor's or cannabis dispensing facility's ability to operate after multi-million dollar capital investments. For that reason, there must be a limitation to facilities in existence at the time a processor or dispensing facility is issued a conditional permit.

1. For violations of relating to distance and zoning restrictions on outdoor advertising, the Board shall give the advertiser written notice to take corrective action to either bring the advertisement into compliance with this section and Board regulations or to remove such advertisement. If corrective action is not taken within 30 days, the pharmaceutical processor will be fined not more than \$1,000.

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H. Signs placed on the property of a pharmaceutical processor or cannabis dispensing facility shall not:

1. Display imagery of cannabis or the use of cannabis or utilize long luminous gas-discharge tubes that contain rarefied neon or other gases;
2. Draw undue attention to the facility but may be designed to assist registered patients, parents, legal guardians and registered agents to find the pharmaceutical processor or cannabis dispensing facility; or
3. Be illuminated during non-business hours.

I. All outdoor signage must be in compliance with local or state requirements.

~~J. A pharmaceutical processor or cannabis dispensing facility shall not advertise at any sporting event or use any billboard advertisements. A pharmaceutical processor may use billboard advertisements or advertise at sporting events if such advertisements are meant to educate or notify the public of the contact information and location of a facility. Such advertising must adhere to the requirements of 18VAC110-60-215(C).~~

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~~K. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location. Cannabis product advertising may be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location if such advertisements are meant to educate or notify the public of the contact information and location of a facility. Such advertising must adhere to the requirements of 18VAC110-60-215(C).~~

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18VAC110-60-220. Pharmaceutical processor or cannabis dispensing facility prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis oil products in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;
2. Sell, deliver, transport, or distribute Cannabis, including cannabis oil products, to any other facility except for wholesale distribution between pharmaceutical processors and to a cannabis dispensing facility pursuant to 18VAC110-60-251;
3. Produce or manufacture cannabis oil products for use outside of Virginia; or
4. Provide cannabis oil products samples.

B. No cannabis dispensing facility shall:

1. Dispense cannabis products in any place except the approved facility at the address of record on the application for the cannabis dispensing facility permit;

2. Sell, deliver, transport, or distribute cannabis products to any other facility, except that it may distribute cannabis products back to the pharmaceutical processor from which it obtained the products or distribute cannabis products between cannabis dispensing facilities; or

3. Provide cannabis products samples.

C. Except for certain employee access to secured areas designated for cultivation and production, in addition to those other areas and authorized by the PIC responsible party pursuant to § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor or cannabis dispensing facility shall be open or in operation, and no person shall be in the dispensing area of a pharmaceutical processor or in a cannabis dispensing facility, unless a pharmacist is on the premises and directly supervising the activity within the dispensing area of the pharmaceutical processor or a cannabis dispensing facility. At all other times, the dispensing area of the pharmaceutical processor or the cannabis dispensing facility shall be closed and properly secured.

~~C. D. No pharmaceutical processor or cannabis dispensing facility shall sell anything other than cannabis oil products from the pharmaceutical processor except for devices for administration of dispensed products or hemp-based CBD products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280.~~

~~D. A pharmaceutical processor shall not advertise cannabis oil products, except it may post the following information on websites:~~

~~1. Name and location of the processor;~~

~~2. Contact information for the processor;~~

~~3. Hours and days the pharmaceutical processor is open for dispensing cannabis oil products;~~

~~4. Laboratory results;~~

~~5. Product information and pricing; and~~

~~6. Directions to the processor facility.~~

E. No cannabis oil products shall be consumed on the premises of a pharmaceutical processor or cannabis dispensing facility, except for emergency administration to a registered patient.

F. No person except a pharmaceutical processor or cannabis dispensing facility employee or a registered patient, parent, or legal guardian, registered agent or a companion of a patient shall be allowed on the premises of a processor or facility with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis or cannabis oil products samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor or cannabis dispensing facility employee prior to entering the pharmaceutical processor or facility.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility and shall return the visitor

identification badge to a ~~pharmaceutical processor~~ an employee upon exiting the ~~pharmaceutical processor or facility~~.

3. All visitors shall log in and out. The pharmaceutical processor or cannabis dispensing facility shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor or cannabis dispensing facility to obtain a waiver from the board, the processor or facility shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor or cannabis dispensing facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

H. No cannabis ~~or~~ products shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor or cannabis dispensing facility, except that a registered parent or legal guardian, or registered agent or an agent of the processor or cannabis dispensing facility may deliver cannabis ~~or~~ products to the registered patient or in accordance with 18VAC110-60-310 A.

I. Notwithstanding the requirements of subsection F of this section, an agent of the board or local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor or cannabis dispensing facility if necessary to perform their governmental duties.

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabis oil products for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall:

~~1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days; and~~

~~2. Not not maintain cannabis oil product in excess of the quantity required for normal, efficient operation;~~

B. At no time shall a cannabis dispensing facility maintain cannabis products in excess of the quantity required for normal, efficient operation.

C. Items a pharmaceutical processor shall properly secure include Cannabis plants, seeds, parts of plants, extracts and cannabis products. A cannabis dispensing facility shall properly secure cannabis products. To secure these items a pharmaceutical processor and a cannabis dispensing facility shall:

~~3. 1. Maintain all Cannabis plants, seeds, parts of plants, extracts, and cannabis oil products in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;~~

~~4. 2. Store all cut parts of Cannabis plants, extracts, or cannabis oil products in an approved safe or approved vault within the pharmaceutical processor or cannabis dispensing facility and not sell cannabis oil products when the pharmaceutical processor or cannabis dispensing facility is closed;~~

~~5. 3. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabis oil products securely locked or protected from entry, except for the actual time~~

required to remove or replace the Cannabis, seeds, parts of plants, extracts, or cannabis oil products;

6. 4. Keep all locks and security equipment in good working order; and

7. 5. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the dispensing area to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility.

8. 6. Not allow keys to be left in the locks or accessible to non-pharmacists persons not authorized by the PIC or responsible party.

D. Access to keys, outside of operating hours, or codes in areas of a pharmaceutical processor that designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or persons supervising cultivation-related or production-related activities at the processor.

B. E. The pharmaceutical processor or cannabis dispensing facility shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, or cannabis oil products. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor or cannabis dispensing facility. The installation and the device shall be based on accepted alarm industry standards and subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other generally accepted and suitable device;
2. The device shall be monitored in accordance with accepted industry standards, be maintained in operating order, have an auxiliary source of power, and be capable of

1. sending an alarm signal to the monitoring entity when breached if the communication line is not operational;

3. The device shall fully protect the entire processor or facility and shall be capable of detecting breaking by any means when activated;

4. The device shall include a duress alarm, a panic alarm, and an automatic voice dialer; and

5. Access to the alarm system for the dispensing area of the processor or cannabis dispensing facility shall be restricted to the pharmacists working at the pharmaceutical processor or cannabis dispensing facility, and the system shall be activated whenever the pharmaceutical processor or facility is closed for business. Access to the alarm system in areas of a pharmaceutical processor that designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor

G. F. A pharmaceutical processor or cannabis dispensing facility shall keep the outside perimeter of the premises well-lit. A processor or facility shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, or cannabis oil products and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

1. The processor or facility shall direct cameras at all approved safes, approved vaults, dispensing areas, or cannabis oil products sales areas, and any other area where Cannabis plants, seeds, extracts, or cannabis oil products are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor or facility shall

angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

2. The video system shall have:

a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor or facility within five minutes of the failure, either by telephone, email, or text message;

b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image, live or recorded;

c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

d. The ability to remain operational during a power outage;

3. All video recordings shall allow for the exporting of still images in an industry standard image format. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmaceutical processor or cannabis dispensing facility shall erase all recordings prior to disposal or sale of the facility; and

4. The processor or facility shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor or facility is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor or facility shall retain an unaltered copy of the

recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor or cannabis dispensing facility PIC that it is not necessary to retain the recording.

D. G. The processor or facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every six months.

E. H. A pharmaceutical processor or cannabis dispensing facility shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor or facility shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor or facility. The pharmaceutical processor or cannabis dispensing facility shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

F. I. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, or cannabis oil products has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

18VAC110-60-251. Wholesale distribution of cannabis oil products.

A. Cannabis oil, cannabis products, botanical cannabis, and usable cannabis from a batch that passed (i) the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests if cannabis oil, extracts, or oil-based products, and/or (ii) for botanical cannabis microbiological, mycotoxin, heavy metal, pesticide chemical residue, the water activity and moisture content for usable cannabis and botanical cannabis products, may be wholesale distributed between pharmaceutical processors when and are packaged and labeled for sale marked for wholesale distribution with all necessary batch and lot identifying information,

~~including harvest date, testing date(s), processing or manufacturing date(s) and an appropriate expiration date in accordance with 18VAC110-60-300 to the extent possible and appropriate. may be wholesale distributed between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility.~~

~~B. Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between cannabis dispensing facilities. Botanical cannabis products from a batch that passed the microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity and moisture content tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between cannabis dispensing facilities.~~

~~C. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor or cannabis dispensing facility distributing the product and the processor or cannabis dispensing facility receiving the product, and (iii) the kind and quantity of product being distributed. The record of the transaction shall be maintained by the distributing pharmaceutical processor or cannabis dispensing facility with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or facility receiving the product in its records of receipt. Such records shall be maintained by each processor or facility for three years in compliance with 18VAC110-60-260.~~

~~D. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared~~

upon request to registered patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

E. A pharmaceutical processor or cannabis dispensing facility wholesale distributing products shall store and handle products and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

F. If a pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products uses an electronic system for the storage and retrieval of records related to distributing cannabis products, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

Part VI

Cultivation, Production, and Dispensing of Cannabis Oil Products

18VAC110-60-285. Registration of products.

A. A pharmaceutical processor shall assign a brand name to each product of cannabis oil. The pharmaceutical processor shall register each brand name with the board on a form prescribed by the board prior to any dispensing and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);
2. Tetrahydrocannabinol acid (THC-A);
3. Cannabidiols (CBD); and
4. Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 90% to 110%.

C. The board shall not register any brand name that:

1. Is identical to or confusingly similar to the name of an existing commercially available product protected by trademark or commonly known in the Virginia medical cannabis market;
2. Is identical to or confusingly similar to the name of an unlawful product or substance;
3. Is confusingly similar to the name of a previously approved cannabis oil product brand name protected by trademark or commonly known in the Virginia medical cannabis market;
4. Is obscene or indecent as defined by the United States Supreme Court;
5. May encourage the use of marijuana or cannabis oil products for recreational purposes such that it would violate the regulations governing advertising;
6. May encourage the use of cannabis oil products for a disease or condition other than the disease or condition the practitioner intended to treat as demonstrated by words or imagery that would violate the regulations governing advertising;
7. Is customarily associated with persons younger than the age of 18 as demonstrated by words or imagery that would violate the regulations governing advertising; or
8. Is related to the benefits, safety, or efficacy of the cannabis oil product unless supported by substantial evidence or substantial clinical data.

D. The Board shall register all cannabis products that meet testing, labeling, and packaging standards.

Commented [SP13]: The redlining in this section is necessary to effectuate SB 1933 and specifically the language set forth in the new Subsection D below.

Commented [HJ14]: Consistent with SB1933.

i. In reviewing an application for product registration, location, font, style and other characteristics of text and graphical information appearing on a label shall be outside the scope of review except to the extent that the Board shall confirm that required label information is present.

ii. To deny or delay product registration, the Board shall within 15 days after receipt of an application for product registration, provide the applicant with the grounds for denial or delay in writing. Such writing must include a citation to a specific law or regulation that would be violated if the application for product registration were approved. The applicant shall have 10 days to respond to the Board's notice.

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E. A pharmaceutical processor's logo and trademark, including the extent to which the same may appear on a product label or package, shall be outside the scope of review during the product registration process. Logos and trademarks shall be evaluated within 15 days of use within the Commonwealth of Virginia under advertising rules.

18VAC110-60-290. Labeling of batch of cannabis oil products.

A. Cannabis oil products produced as a batch shall not be adulterated.

B. Cannabis oil products produced as a batch shall be:

1. Processed, packaged, and labeled according to the U.S. Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 CFR Part 111; and

2. Labeled with:

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabis oil product that was registered with the board pursuant to 18VAC110-20-285;

c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;

d. The date of testing and packaging;

e. The expiration date which shall be six months or less from the date of packaging, unless supported by based-on stability testing;

f. The quantity of cannabis oil products contained in the batch;

g. A terpenes profile and a list of all active ingredients, including:

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD); and

(4) Cannabidiolic acid (CBDA); and

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

h. A-For extract and oil-based cannabis products, the potency and a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis; and

i. For botanical cannabis products, the potency and a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, pesticide chemical residue analysis of water activity, and moisture content analysis;

C. A label shall satisfy all necessary labeling requirements if Subsections A and B are met based on the presence and verification of batch and lot identifying information and consistency with an approved formulation or previous product registration based upon certificates of

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analysis provided by a testing laboratory. Labeling shall be deemed to satisfy such requirements within 15 days of receipt of a request for product registration unless the Board notifies the processor of a specific deficiency and provides a citation therefore.

18VAC110-60-300. Laboratory requirements; testing.

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis ~~oil~~ products unless such laboratory:

1. Is independent from all other persons involved in the cannabis oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, cannabis dispensing facility, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis oil products; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the ISO/IEC 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration

Commented [SP15]: Comment: the Board should consider requiring testing labs to affirmatively represent their independence because it is impossible for processors to fulsomely evaluate and come to an accurate, reliable conclusion as to the requirements of independence – but processors and patients will suffer the consequences of a lab's failure to remain independent because less product will be available and the cost of medicine will increase/remain high.

method utilized to perform a Cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use nonaccredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use nonaccredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize non-accredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within twenty-four hours. The laboratory shall immediately stop handling, testing or analyzing Cannabis for pharmaceutical processors.

5. Complies with a transportation protocol for transporting Cannabis or cannabis products to or from itself or to or from pharmaceutical processors.

6. A laboratory will prepare and submit to the Board for approval a security plan describing the practices, procedures and equipment it will use to protect cannabis, usable cannabis or cannabis products against theft, loss and diversion. Such plan shall set forth in detail how the laboratory will ensure each employee involved in the testing process or who has access to active cannabis material in any form does not have a felony conviction within the last 5 years and the means by which the laboratory will connect with the processors's and the Board's electronic tracking systems.

B. ~~After processing and before dispensing the any cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue, and, for botanical cannabis, the water activity and moisture content, and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The same must be representative of the entire batch to include selection from various points in the batch container and be of sufficient sample size to allow for analysis of all required tests.~~
Cannabis oil products and botanical cannabis products will be tested according to the following:

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1. ~~From each homogenized batch of cannabis oil product, a pharmaceutical processor shall make a sample available for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue, and~~

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(ii) conduct an active ingredient analysis and terpene profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis, unless the laboratory indicates a smaller sample is statistically sufficient.

Commented [HJ16]: 0.5% is a massive sample which potentially carries significant expense. For instance, [these sample ranges](#) seem more reasonable.

2. From each harvest batch of botanical cannabis product, a pharmaceutical processor shall make a sample available for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, water activity and moisture content. In determining the minimum sample size for testing from each harvest batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The sample must be representative of the entire batch to include selection from various points in the batch and be of sufficient sample size to allow for analysis of all required tests. Testing of a harvest batch of botanical cannabis to be processed into cannabis oil ~~is shall not be~~ required. The processed cannabis oil will be tested according to subsection 1 above.

Commented [HJ17]: It is important that this procedure is retained as it avoids unnecessary testing and waste. Testing for this material should occur after processing.

3. All cannabis products will be tested in accordance with the requirements of this subsection.

4. Upon request, a pharmaceutical processor or cannabis dispensing facility may request voluntary laboratory analysis of cannabis, usable cannabis, and other materials to verify an original testing laboratory's findings or to evaluate ~~constituents, environmental factors, formulations in development, and the like~~. Testing performed under this provision shall be performed pursuant to a private agreement between the pharmaceutical processor or cannabis dispensing facility and the laboratory and shall not be subject to mandatory reporting of any type or kind.

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Commented [SP18]: e.g., growing media, water, plant genetics, etc.

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C. From the time that a batch of cannabis oil product has been ~~homogenized for sample~~ ~~sampled for~~ testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any cannabis oil products and materials upon the completion of any testing, use, or research.

F. ~~If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken, batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvents, and an active ingredient analysis and terpenes profile shall be conducted. A batch of botanical cannabis that is tested in the same manner, with the addition of water activity and moisture content, may be remediated by the pharmaceutical processor if it does not pass testing requirements. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all testing standards set forth in this section. If a sample of a cannabis oil product does not pass the~~

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Commented [HJ19]: Solvent testing is not needed for botanical cannabis.

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microbiological, mycotoxin, heavy metal, pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the batch may be remediated with further processing and submitted for retesting. If a sample of botanical cannabis fails testing requirements for microbiologicals, mycotoxins, heavy metals, pesticide chemical residue, water activity, and moisture content, the processor may remediate the batch and submit a sample for retesting. Retesting is necessary only for the previously failed criteria. If the batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all applicable testing standards.

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Commented [SP20]: We could also add heavy metals if it would make the Board more comfortable (to the extent Board comfort remains an issue).

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1. For purposes of the microbiological test, a cannabis oil product sample which is a cannabis oil product shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia. Botanical cannabis shall be deemed to have passed microbiological testing if it satisfies the action limits of 10,000 CFU/g of total yeast and molds and 100,000 CFU/g of total aerobic bacteria.

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2. For purposes of the mycotoxin test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)

Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

- a. Tetrahydrocannabinol (THC);
- b. Tetrahydrocannabinol acid (THC-A);
- c. Cannabidiols (CBD); and
- d. Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.

7. For the purposes of water activity and moisture content for botanical cannabis, the product shall be deemed to have passed if the water activity rate does not exceed 0.765Aw and the moisture content does not exceed 15 percent.

Commented [HJ21]: 0.7 aw is recommended as the limit, although most of our product will be less than 0.65 aw. This allows for a small buffer in case moisture is added back to the product through the transport/sampling process.

G. If a sample of cannabis oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests, and for botanical cannabis, microbiological, mycotoxin, heavy metal, pesticide chemical residue, also the water activity and moisture content tests, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products, except stability testing shall not be required for cannabis oil products if the pharmaceutical processor assigns an expiration date of six months or less from the date of packaging. *Botanical cannabis products shall have an expiration date of one year or less from the date of the laboratory testing certificate of analysis.*

H. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test, and, for botanical cannabis, microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity and moisture content, water activity or moisture content, at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board. *Testing performed under Subsection (B)(4) hereof shall be exempt from this requirement.*

I. *Except for testing performed under Subsection (B)(4), each pharmaceutical processor or cannabis dispensing facility shall have such laboratory results available upon request to registered patients, parents or legal guardians, registered agents, and registered practitioners who have certified qualifying patients, the board, or an agent of the board.*

18VAC110-60-310. Dispensing of cannabis oil products.

A. A pharmacist in good faith may dispense cannabis oil products to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of cannabis oil products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view, in person or by audiovisual means, a current photo identification of the patient, parent, or legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis oil products to the registered patient.

2. The A pharmacist or pharmacy technician employed by the processor or cannabis dispensing facility shall make and maintain for three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible and shall maintain it on site or by electronic means for two years.

3. Prior to any subsequent dispensing, the pharmacist, or pharmacy technician, or delivery agent shall view verify that the current written certification and on file has not expired. An employee or delivery agent shall view a current photo identification and current registration of the patient, parent, or legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the pharmaceutical processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis oil product. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis

oil products at any time except that no registered patient, parent, or legal guardian, or registered agent shall receive more than a 90-day supply of cannabis oil products for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. However, no more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. In determining the appropriate amount of cannabis product to be dispensed to a patient, a pharmacist shall consider all cannabis products dispensed and adjust the amount dispensed accordingly.

Commented [SP22]: Comment: the Board should consider exclusionary language in this provision that contemplates legal possession. Specifically, while a permittee may not dispense more than the quantity identified, given legal possession, the Board should clarify that a patient found in possession of a larger quantity is responsible for exceeding the possession threshold as opposed to the permittee or its associated licensed professionals (particularly the PIC).

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil cannabis product that contains:

1. A serial number assigned to the dispensing of the oil product;
2. The brand name of cannabis oil product that was registered with the board pursuant to 18VAC110-60-285 and its strength;
3. The serial number assigned to the oil product during production;
4. The date of dispensing the cannabis oil product;
5. The quantity of cannabis oil products dispensed;
6. A terpenes profile and a list of all active ingredients, including:
 - a. Tetrahydrocannabinol (THC);
 - b. Tetrahydrocannabinol acid (THC-A);
 - c. Cannabidiol (CBD); and
 - d. Cannabidiolic acid (CBDA);

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

7. A pass rating based on the laboratory's analysis as follows:

a. for extracts and oil-based products: microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis; and
b. for botanical cannabis products: microbiological, mycotoxins, heavy metals, pesticide chemical residue analysis, and water activity and moisture content analysis;

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8. The name and registration number of the registered patient;

9. The name and registration number of the certifying practitioner;

10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;

~~14.~~ 12. The name or initials of the dispensing pharmacist;

~~12.~~ 13. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;

~~13.~~ 14. Any necessary cautionary statement; and

~~14.~~ 15. A prominently printed expiration date based on stability testing and the pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. A pharmaceutical processor shall not label cannabis oil products as "organic" unless the Cannabis plants have been organically grown and the cannabis oil products have been produced,

processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.

E. The cannabis ~~oil~~ products shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

F. No person except a pharmacist or a pharmacy technician operating under the direct supervision of a pharmacist shall alter, deface, or remove any label so affixed.

G. A pharmacist shall be responsible for verifying the accuracy of the dispensed ~~oil~~ product in all respects prior to dispensing and shall document that each verification has been performed.

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis ~~oil~~ products in treating the registered patient's diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis ~~oil~~ products to a registered patient, parent, or legal guardian, or registered agent if the pharmacist suspects that dispensing cannabis ~~oil~~ products to the registered patient, parent, or legal guardian, or registered agent may have negative health or safety consequences for the registered patient or the public.

18VAC110-60-321. Devices, hemp-based CBD products, and inert product samples.

A. A pharmaceutical processor or cannabis dispensing facility may have for sale, on-site, devices intended for the administration of dispensed cannabis products and hemp-based CBD

products that meet the applicable standards set forth in state ~~and~~ federal law ~~and that meet testing requirements of 18VAC110-60-280.~~

B. The pharmaceutical processor or cannabis dispensing facility may use and distribute inert product samples that do not contain any active cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility ~~to potential and registered patients, parents, or legal guardians, or agents~~ without the need for a written certification. Such inert product samples may not be sold or further distributed.

18VAC110-60-330. Disposal of cannabis oil products.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, ~~misbranded, or deteriorated cannabis products and green waste including all active and potentially active cannabis such as usable cannabis, extracts, and cannabis products as applicable. Green waste includes Cannabis plants, including seeds, and parts of plants, extracts, or cannabis oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabis oil nonrecoverable. Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render it the mixture materially inactive and unrecognizable. Once rendered unrecognizable, green waste shall be considered agricultural waste and may be disposed of accordingly.~~

Commented [SP23]: Comment: the term "misbranded" is a term of art under federal law and its meaning is incompatible with medicinal cannabis product manufacturing in several ways. To that end, "misbranded" should be (i) omitted from this provision; (ii) defined in the regulations in a manner that makes it relevant and appropriate in the context of medical cannabis product manufacturing; or (iii) replaced with a word that is not a term of art under federal law, such as "unregistered."

Commented [SP24]: Comment: this provision would benefit from clarification which can be accomplished by using the terms defined in statute. For example, "usable cannabis" captures Cannabis plants, seeds, and parts of plants.

B. The destruction and disposal of cannabis products and green waste, extracts, and cannabis oil products, as applicable, shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor ~~at two pharmacist and at least one other employees of the pharmaceutical processor or cannabis dispensing facility, respectively,~~ and shall be conducted under video surveillance. The persons ~~destroying and~~ disposing of ~~the such cannabis products or green waste, extracts, or cannabis oil products~~ shall maintain and make available a separate record of each ~~such destruction and~~ disposal indicating:

Commented [SP25]: Comment: see 54.1-3442.6(C)(b), which requires the Board to adopt requirements RE: secure disposal & agricultural waste. Security is achieved through weighing, grinding, rendering unrecognizable, and recording green waste destruction. However, this provisions should clarify that once rendered green waste shall be treated as agricultural waste.

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1. The date and time of destruction and disposal;
2. The manner of destruction and disposal;
3. The name and quantity of ~~cannabis oil~~ cannabis product(s) or green waste destroyed
and disposed of; and
4. The signatures of the persons destroying or and disposing of the cannabis product(s)
or green waste, as applicable green waste, extracts, or cannabis oil products.

C. The record of disposal shall be maintained at the pharmaceutical processor or cannabis
dispensing facility for three years from the date of destruction and disposal.



June 14, 2021

Virginia Board of Pharmacy Laws & Regulations

Public hearing Draft Proposed Regulations Governing Pharmaceutical Processors

Dear Chair and Board Members,

I am Randy Query, Director of Government Relations for the American Association for Laboratory Accreditation (A2LA). I have been involved with laboratory accreditation for well over two decades. On behalf of the A2LA, I am commenting on the proposed Draft Regulations Governing Pharmaceutical Processors.

By way of background, A2LA is a non-profit, accreditation body with over 3800 actively accredited certificates representing all 50 states including over ninety organizations accredited for cannabis testing. We have been granting accreditation to testing laboratories in various industries since 1979. The criteria forming the basis for our laboratory accreditation program is ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories. We ourselves, as an accreditation body, have been evaluated against rigorous standards in providing this accreditation service and are recognized globally as an International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation body.

In establishing an adult-use cannabis program, laboratory testing and the ensuing test results, are critical to the program. Regular laboratory assessments leading to accreditation, will provide the users of the test reports with confidence that the data is backed by a quality management system, technically competent testing, qualified personnel, and the use of the appropriate facilities and testing equipment.

We *strongly* support your regulation in section 18VAC110-60-300 A. that requires ISO/IEC 17025 Accreditation through an ILAC signatory as required in section 18VAC110-60-300.

We recommend that section 18VAC110-60-300, B. (page 63) of the proposed rules clearly state that the sample collection of cannabis regulated under this rule, be collected by the accredited cannabis testing laboratory. This will ensure that the sample is collected appropriately and objectively, by an impartial sampling agent. The accredited cannabis testing laboratory can be assessed by an accreditation body to ensure that the cannabis testing laboratory has appropriate sampling procedures and are implementing the appropriate sampling procedures using trained personnel.

These accredited cannabis testing laboratories will be analyzing the cannabis for contaminants such as heavy metals, microbiological and mycotoxin and pesticides chemical residues. The accredited testing will help assure that the data is supported by technical competent staff using validated methods and calibrated instruments.

We would be pleased to provide more background and elaborate on our comments at your convenience. If interested please contact me at rquery@A2LA.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Randy Query', is written over a white rectangular area. The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Randall Query

Director of Government Relations, A2LA

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Board Of Pharmacy

Exempt action - 2021 legislation

Chapter 60

Regulations Governing Pharmaceutical Processors

Part I

General Provisions

18VAC110-60-10. Definitions.

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"90-day supply" means the amount of cannabis oil products reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation, of visual, oral, or written communication, through any means, to directly induce any person to patronize a particular pharmaceutical processor or cannabis dispensing facility, or to purchase particular approved cannabis products. Advertising includes marketing.

"Batch" means a quantity of (i) cannabis oil from a production lot or (ii) harvested botanical cannabis product that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabis oil products for treatment of

or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Dispensing error" means one or more of the following was discovered after the final verification by the pharmacist, regardless of whether the patient received the ~~an~~ product:

1. Variation from the intended ~~an~~ product to be dispensed, including:
 - a. Incorrect ~~an~~ product;
 - b. Incorrect ~~an~~ product strength;
 - c. Incorrect dosage form;
 - d. Incorrect patient; or
 - e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
 - a. Known therapeutic duplication;
 - b. Known drug-disease contraindications;
 - c. Known drug-drug interactions;
 - d. Incorrect drug dosage or duration of drug treatment;
 - e. Known drug-allergy interactions;
 - f. A clinically significant, avoidable delay in therapy; or
 - g. Any other significant, actual, or potential problem with a patient's drug therapy.
3. Delivery of ~~an~~ ~~an~~ a cannabis product to the incorrect patient.
4. An act or omission relating to the dispensing of cannabis ~~an~~ product that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis oil product is sold to a registered patient, parent, or legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

"On duty" means that a pharmacist, the responsible party, or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"Perpetual inventory" means an ongoing system for recording quantities of cannabis oil received, dispensed, or otherwise distributed by a cannabis dispensing facility.

"PIC" means the pharmacist-in-charge designated on the pharmaceutical processor or cannabis dispensing facility application who shall have oversight of the processor's dispensing area or cannabis dispensing facility.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana for the creation of usable cannabis, botanical cannabis or a cannabis product derived thereof, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis,

or (iii) by a combination of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Qualifying patient" means a Virginia resident who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabis ~~oil~~ products for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis ~~oil~~ products to such patient.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Responsible party" means the person designated on the pharmaceutical processor application who shall have oversight of the cultivation and production areas of the pharmaceutical processor.

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

Room or Phase	Temperature	Humidity
Mother room	65 - 75° <u>85°</u> F	50% - 60% <u>75%</u>
Nursery phase	71 <u>65</u> - 85° F	65% <u>50%</u> - 75%
Vegetation phase	71 <u>65</u> - 85° F	55% <u>50%</u> - 65% <u>75%</u>
Flower/harvest phase	71 <u>65</u> - 85° F	55% <u>40%</u> - 60% <u>75%</u>
Drying/extraction rooms	< 75° F	55% <u>40%</u> - 60% <u>75%</u>

"Temporarily resides" means a person that does not maintain a principle place of residence within Virginia but resides in Virginia on a temporary basis as evidenced by documentation substantiating such temporary residence.

18VAC110-60-20. Fees.

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

1. Initial registration.	\$50
2. Annual renewal of registration.	\$50
3. Replacement of registration for a qualifying practitioner whose information has changed or whose original registration certificate has been lost, stolen, or destroyed.	\$50

C. Registration by a qualifying patient, parent, or legal guardian, or registered agent.

1. Initial registration of a patient.	\$50
2. Annual renewal of registration of a patient.	\$50
3. Initial registration of a parent or legal guardian.	\$25
4. Annual renewal of registration of a parent or guardian.	\$25
5. <u>Initial registration or annual renewal of a registered agent</u>	\$25
6. <u>Replacement of registration for a qualifying patient, parent, or legal guardian, or registered agent whose original registration certificate has been lost, stolen, or destroyed.</u>	\$25

D. Pharmaceutical processor permit.

1. Application.	\$10,000
2. Initial permit.	\$60,000
3. Annual renewal of permit.	\$10,000
4. Change of name of processor.	\$100
5. Change of PIC <u>or responsible party</u> or any other information provided on the permit application.	\$100
6. Change of ownership not requiring a criminal background check.	\$100
7. Change of ownership requiring a criminal background check.	\$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	\$1,000

9. Reinspection fee.	\$1,000
10. Registration of each cannabis oil product.	\$25

E. Cannabis dispensing facility permit.

<u>1. Initial permit.</u>	<u>\$5,000</u>
<u>2. Annual renewal of permit.</u>	<u>\$1,500</u>
<u>3. Change of name of dispensing facility.</u>	<u>\$100</u>
<u>4. Change of PIC or any other information provided on the permit application.</u>	<u>\$100</u>
<u>5. Change of ownership not requiring a criminal background check.</u>	<u>\$100</u>
<u>6. Change of ownership requiring a criminal background check.</u>	<u>\$250</u>
<u>7. Any acquisition, expansion, remodel, or change of location requiring an inspection.</u>	<u>\$1,000</u>
<u>8. Reinspection fee.</u>	<u>\$1,000</u>

E. F. The handling fee for returned check or dishonored credit card or debit card shall be \$50.

Part II

Requirements for Practitioners and Patients

18VAC110-60-30. Requirements for practitioner issuing a certification.

A. Prior to issuing a certification for cannabis oil products for any diagnosed condition or disease, the practitioner shall meet the requirements of § 54.1-3408.3 of the Code of Virginia, shall submit an application and fee as prescribed in 18VAC110-60-20, and shall be registered with the board.

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition;
2. Diagnose the patient;

3. Be of the opinion that the potential benefits of cannabis ~~oil~~ products would likely outweigh the health risks of such use to the qualifying patient;

4. Authorize on the written certification the use of botanical cannabis for a minor patient if the practitioner determines such use is consistent with the standard of care to dispense botanical cannabis to a minor. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing. The pharmacist shall maintain documentation of such authorization.

~~4.~~ 5. Explain proper administration and the potential risks and benefits of the cannabis ~~oil~~ products to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

~~5.~~ 6. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabis ~~oil~~ products for treating the diagnosed condition or disease;

~~6.~~ 7. Comply with generally accepted standards of medical practice, except to the extent such standards would counsel against certifying a qualifying patient for cannabis ~~oil~~ products;

~~7.~~ 8. Maintain medical records in accordance with 18VAC85-20-26 for all patients for whom the practitioner has issued a certification; and

~~8.~~ 9. Access or direct the practitioner's delegate to access the Virginia Prescription Monitoring Program of the Department of Health Professions for the purpose of determining which, if any, covered substances have been dispensed to the patient.

C. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation, which may include the use of telemedicine, provided that the use of telemedicine:

1. Includes the delivery of patient care through real-time interactive audio-visual technology;

2. Conforms to the standard of care expected for in-person care; and

3. Transmits information in a manner that protects patient confidentiality.

Such telemedicine use shall be consistent with federal requirements for the prescribing of Schedules II through V controlled substances.

D. A practitioner shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a certification. Employees under the direct supervision of the practitioner may assist with preparing a certification, so long as the final certification is approved and signed by the practitioner before it is issued to the patient.

E. The practitioner shall provide instructions for the use of cannabis oil products to the patient, parent, or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

F. A practitioner shall not issue certifications for cannabis oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

G. Upon request, a practitioner shall make a copy of medical records available to an agent of the Board of Medicine or Board of Pharmacy for the purpose of enabling the board to ensure compliance with the law and regulations or to investigate a possible violation.

18VAC110-60-40. Prohibited practices for practitioners.

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis ~~oil~~ products;
2. Offer a discount or any other thing of value to a qualifying patient, parent, ~~or~~ guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis ~~oil~~ product;
3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis ~~oil~~ products are dispensed or produced; or
4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor, a cannabis dispensing facility, or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabis ~~oil~~ products, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabis ~~oil~~ product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabis ~~oil~~ other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. Registration of a patient, parent, or legal guardian or registered agent.

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;
2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt or proof of temporary residency, if applicable, such as a current academic identification card from a Virginia institution of higher learning, rental agreement, utility bill, or attestation on a form prescribed by the board that contains information sufficient to document temporary residency in Virginia;
3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;
4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;
5. Payment of the appropriate fees; and
6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

B. A patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis products on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, birthdate, and registration number of each registered patient for whom the individual intends to act as a registered agent;

2. Proof of identity in the form of a copy of a government-issued identification card;

3. Payment of the applicable fee; and

4. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

~~B. C.~~ A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

~~C. D.~~ Patients, parents, and legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabis ~~oil~~ products.

18VAC110-60-60. Denial of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent application.

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;

2. Does not provide acceptable proof of identity, residency or temporary residency, or age of the patient to the board;

3. Provides false, misleading, or incorrect information to the board;

4. Has had a qualifying registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent denied, suspended, or revoked by the board in the previous six months;

5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabis ~~oil~~ products; or

6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient, parent, or legal guardian, or registered agent applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-70. Reporting requirements for practitioners, patients, parents, or legal guardians, or registered agents.

A. A practitioner shall report to the board, on a form prescribed by the board, the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabis ~~oil~~ products or the practitioner's inability to continue treating the patient. A practitioner shall report such death, change of status, or inability to continue treatment not more than 15 days after the practitioner becomes aware of such fact.

B. A patient, parent, or legal guardian who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change. The patient, parent, or legal guardian shall report changes that include a change in name, address, contact information, medical status of the patient, or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

D. If a patient, parent, or legal guardian, or registered agent notifies the board of any change that results in information on the registration of the patient, parent, or legal guardian's ~~registration~~

guardian, or registered agent being inaccurate, the board shall issue a replacement registration. Upon receipt of a new registration, the qualifying patient, parent, ~~or legal guardian,~~ or registered agent shall destroy in a nonrecoverable manner the registration that was replaced.

~~D.~~ E. If a patient, parent, ~~or legal guardian,~~ or registered agent becomes aware of the loss, theft, or destruction of the registration of such patient, parent, ~~or legal guardian,~~ or registered agent, the ~~patient, parent, or legal guardian~~ registrant shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

18VAC110-60-80. Proper storage and disposal of ~~cannabidiol oil or THC-A oil~~ cannabis products by patients, parents, ~~or legal guardians,~~ or registered agents.

A. A registered patient, parent, ~~or legal guardian,~~ or registered agent shall exercise reasonable caution to transport and store cannabis oil products in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, ~~or legal guardian,~~ or registered agent shall dispose of all usable cannabis oil products in possession of the registered patient, parent, ~~or legal guardian's~~ possession guardian, or registered agent no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabis oil products. A registered patient, parent, ~~or legal guardian,~~ or registered agent shall complete such disposal by one of the following methods:

1. By removing the oil product from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in

a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.

2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, or legal guardian, or registered agent registration.

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, or legal guardian, or registered agent) under the following circumstances:

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;
2. The ~~patient, parent, or legal guardian~~ registrant provided false, misleading, or incorrect information to the board;
3. The ~~patient, parent, or legal guardian~~ registrant is no longer a resident of Virginia or is no longer temporarily residing in Virginia;
4. The ~~patient, parent, or legal guardian~~ registrant obtained more than a 90-day supply of cannabis oil products in a 90-day period or more than four ounces of botanical cannabis within a 30 day period;
5. The ~~patient, parent, or legal guardian~~ registrant provided or sold cannabis oil products to any person, including another registered ~~patient, parent, or legal guardian~~ registrant;

6. The ~~patient, parent, or legal guardian~~ registrant permitted another person to use the registration of the ~~patient, parent, or legal guardian~~ registrant, except as required for a registered agent to act on behalf of a patient;
7. The ~~patient, parent, or legal guardian~~ registrant tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the ~~patient, parent, or legal guardian~~ registrant;
8. The registration of the ~~patient, parent, or legal guardian~~ registrant was lost, stolen, or destroyed, and the ~~patient, parent, or legal guardian~~ registrant failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;
9. The ~~patient, parent, or legal guardian~~ registrant failed to notify the board of a change in registration information or notified the board of such change more than 44 15 days after the change; or
10. The ~~patient, parent, or legal guardian~~ registrant violated any federal or state law or regulation.

Part III

Application and Approval Process for Pharmaceutical Processors and Cannabis Dispensing Facilities

18VAC110-60-100. Publication of notice for submission of applications.

A. The board shall publish a notice of open applications for pharmaceutical processor permits. Such notice shall include information on how to obtain and complete an application, the required fees, the criteria for issuance of a permit, and the deadline for receipt of applications.

B. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

C. The board shall have the right to cancel a notice of open applications prior to the award of a pharmaceutical processor permit.

18VAC110-60-110. Application process for pharmaceutical processor permits.

A. The application process for permits shall occur in three stages: submission of initial application, award of conditional approval, and grant of a pharmaceutical processor permit.

B. Submission of initial application.

1. A pharmaceutical processor permit applicant shall submit the required application fee and form with the following information and documentation:

- a. The name and address of the applicant and the applicant's owners;
- b. The location within the health service area established by the State Board of Health for the pharmaceutical processor that is to be operated under such permit;
- c. Detailed information regarding the applicant's financial position indicating all assets, liabilities, income, and net worth to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis ~~oil~~ products pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;
- d. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis ~~oil~~ products;

- e. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of a permit;
- f. Information necessary for the board to conduct a criminal background check on the applicant;
- g. Information about any previous or current involvement in the medical cannabis ~~oil~~ industry;
- h. Whether the applicant has ever applied for a permit or registration related to medical cannabis ~~oil~~ in any state and, if so, the status of that application, permit, or registration, to include any disciplinary action taken by any state on the permit, the registration, or an associated license;
- i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabis ~~oil~~ products;
- j. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;
- k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the Cannabis plants and ~~oil~~ products; (iii) the location of all areas that may contain Cannabis plants or cannabis ~~oil~~ products; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress;
- l. Documents related to any compassionate need program the pharmaceutical processor intends to offer;

m. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabis oil products and to safely dispense such products; and

n. Such other documents and information required by the board to determine the applicant's suitability for permitting or to protect public health and safety.

2. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the permit selection process.

3. The board shall conduct criminal background checks on applicants and may verify information contained in each application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.

C. In the event the board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in a health service area, the board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

D. No person who has been convicted of a felony ~~or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 of under the Code of Virginia or another jurisdiction within the last five years~~ shall ~~have any form of ownership~~ have 5% or greater ownership, be employed by, or act as an agent of a pharmaceutical processor.

18VAC110-60-120. Conditional approval.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant conditional approval on a competitive basis based on compliance with requirements set forth in 18VAC110-60-110.

B. The board shall consider, but is not limited to, the following criteria in evaluating pharmaceutical processor permit applications:

1. The results of the criminal background checks required in 18VAC110-60-110 B 3 or any history of disciplinary action imposed by a state or federal regulatory agency;
2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school or daycare;
3. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants or the cannabis oil products;
4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabis oil products;
5. The extent to which the applicant or any of the applicant's pharmaceutical processor owners have a financial interest in another license, permit, registrant, or applicant; and
6. Any other reason provided by state or federal statute or regulation that is not inconsistent with the law and regulations regarding pharmaceutical processors.

C. The board may disqualify any applicant who:

1. Submits an incomplete, false, inaccurate, or misleading application;
2. Fails to submit an application by the published deadline;
3. Fails to pay all applicable fees; or
4. Fails to comply with all requirements for a pharmaceutical processor.

D. Following review, the board shall notify applicants of denial or conditional approval. The decision of the board not to grant conditional approval to an applicant shall be final.

E. If granted conditional approval, an applicant shall have one year from date of notification to complete all requirements for issuance of a permit, to include employment of a PIC, responsible party, and other personnel necessary for operation of a pharmaceutical processor, construction or remodeling of a facility, installation of equipment, and securing local zoning approval.

18VAC110-60-130. Granting of a pharmaceutical processor permit.

A. The board may issue a pharmaceutical processor permit when all requirements of the board have been met, to include:

1. Designation of a PIC and responsible party;
2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;
3. Evidence of utilization of an electronic tracking system; and
4. A satisfactory inspection of the facility conducted by the board or ~~its~~ the board's agents.

B. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

C. Before any permit is issued, the applicant shall attest to compliance with all state and local laws and ordinances. A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

E. A pharmaceutical processor shall be deemed to have commenced operation if Cannabis plants are under cultivation by the processor in accordance with the approved application.

F. In the event a permit is rescinded pursuant to this section, the board may award a pharmaceutical processor permit by selecting among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant who applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish in accordance with this section a notice of open applications for a pharmaceutical processor permit.

G. Once the permit is issued, ~~Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application a processor may begin cultivation of Cannabis and the responsible party or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 shall be present during hours of operation to ensure the safety, security and integrity of the Cannabis. Once Cannabis has been placed in the dispensing area of the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC responsible party shall ensure security measures are adequate to protect the cannabis in the cultivation and production area from diversion at all times, and the PIC shall have concurrent responsibility for preventing diversion from the dispensing area.~~ If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist ~~or the responsible party~~ shall continue to be on site on a daily basis.

18VAC110-60-135. Application for and granting of a permit for a cannabis dispensing facility.

A. Pursuant to § 54.1-3442.6 of the Code of Virginia, the board may issue up to five cannabis dispensing facility permits for each health service area. A permit may be issued to a facility that

is owned, at least in part, by the pharmaceutical processor located in that health service area for the dispensing of cannabis products that has been cultivated and produced on the premises of a pharmaceutical processor. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for each cannabis dispensing facility permit shall be submitted to the board, along with the following information and documentation:

1. The name and address of the facility, which shall not be within 1,000 feet of a school or daycare;
2. The name and address of the facility's owners with 5% or greater ownership;
3. Name and signature of pharmacist-in-charge practicing at the facility;
4. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis products; and
5. Information necessary for the board to conduct a criminal background check on the facilities owners with 5% or greater ownership.

C. Prior to issuing the permit, an inspection of the facility shall be performed by an agent of the board. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

D. A cannabis dispensing facility shall comply with all state and local laws and ordinances.

E. A cannabis dispensing facility permit shall not be issued to any person to operate from a private dwelling or residence.

F. No person who has been convicted of a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a cannabis dispensing facility.

G. If the cannabis dispensing facility is not operational within 90 days from the date the permit is issued, the board shall rescind the permit unless an extension is granted for good cause shown.

H. A cannabis dispensing facility shall be deemed to have commenced operation if it is in receipt of cannabis products from a pharmaceutical processor.

I. Once the facility is in possession of cannabis products, a pharmacist shall be on site at all times during the declared hours of operation.

18VAC110-60-136. Denial of a cannabis dispensing facility permit application.

A. The board may deny an application for a cannabis dispensing facility permit if the applicant:

1. Submits an incomplete, false, inaccurate, or misleading application;
2. Fails to pay all applicable fees; or
3. Fails to comply with all requirements for a cannabis dispensing facility.

B. If the board denies an application of cannabis dispensing facility permit, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-140. Notification of changes by pharmaceutical processor or cannabis dispensing facility.

A. Unless otherwise provided in law or regulation, the PIC or the responsible party designated on the application ~~to be in full and actual charge~~ of the pharmaceutical processor or a cannabis dispensing facility shall provide any notification or information that is required from a pharmaceutical processor or a cannabis dispensing facility with respect to their designated areas of oversight.

B. Prior to making any change to the pharmaceutical processor or cannabis dispensing facility name, the pharmaceutical processor or cannabis dispensing facility shall submit an application for such change to the board and pay the fee.

C. Any person wishing to engage in the acquisition of an existing pharmaceutical processor or cannabis dispensing facility, change the location of an existing pharmaceutical processor or cannabis dispensing facility, make structural changes to an existing pharmaceutical processor or cannabis dispensing facility, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

1. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

2. Cannabis, oil acquired from industrial hemp extract, or cannabis products shall not be moved to a new location until approval is granted by the inspector or board staff.

18VAC110-60-150. Pharmaceutical processor or cannabis dispensing facility closings; going out of business; change of ownership.

A. At least 30 days prior to the date a pharmaceutical processor or cannabis dispensing facility closes, either temporarily or permanently, the owner shall:

1. Notify the board;

2. Send written notification to patients with current certification; and

3. Post a notice on the window or door of the pharmaceutical processor or cannabis dispensing facility.

B. The proposed disposition of all Cannabis, oil from industrial hemp, cannabis products, dispensing records, patient information records, and other required records, as applicable, shall be reported to the board. If the Cannabis, cannabis products, and records are to be transferred

to another processor located in Virginia or to another cannabis dispensing facility in the same health service area, the owner shall inform the board and the patients and include on the public notice the name and address of the processor or cannabis dispensing facility to whom the Cannabis, cannabis products, and records are being transferred and the date of transfer.

C. Exceptions to the public notice shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmaceutical processor or cannabis dispensing facility is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as the owner knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

D. In the event of an exception to the notice, the PIC, responsible party, or owner shall provide notice as far in advance of closing as allowed by the circumstances.

E. At least 14 days prior to any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

3. If a new owner's share constitutes 5.0% or greater of the total ownership, the new owner shall submit to fingerprinting and the criminal history record search required by of § 54.1-3442.6 E of the Code of Virginia.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit or a cannabis dispensing facility.

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued; place such permit on probation; place conditions on such permit; or take other actions permitted by statute or regulation on the following grounds:

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabis ~~oil~~ products that is authorized under state law and regulations;
2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;
3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabis ~~oil~~ products, or other controlled substances;
4. Intentionally or through negligence obscuring, damaging, or defacing a permit or registration card;
5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, ~~or~~ legal guardian or registered agent, except as required for a registered agent to act on behalf of a patient;
6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor; or

7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown upon a written request from a pharmaceutical processor or cannabis dispensing facility. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or ~~production~~ cannabis dispensing facility.

Part IV

Requirements for Pharmaceutical Processor Personnel

18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations.

A. A pharmacist with a current, unrestricted license issued by the board practicing at the location of the address on the pharmaceutical processor or cannabis dispensing facility application shall be in full and actual charge of the dispensing area of a pharmaceutical processor or of a cannabis dispensing facility and shall serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the dispensing area of the pharmaceutical processor or of a cannabis dispensing facility at all times during its hours of operation ~~or whenever the processor is being accessed~~.

C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application, shall have oversight of the cultivation and production areas, and shall possess:

1. A current, unrestricted license as a pharmacist issued by the board;

2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;

3. A certification recognized by the board; or

4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.

~~C.~~ D. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and who has had at least two years of experience practicing as a pharmacy technician may perform the following duties under supervision of a pharmacist:

1. The entry of drug dispensing information and drug history into a data system or other recordkeeping system;
2. The preparation of labels for dispensing the ~~oil~~ cannabis product or patient information;
3. The removal of the ~~oil~~ cannabis product to be dispensed from inventory;
4. The measuring of the ~~oil~~ cannabis product to be dispensed;
5. The packaging and labeling of the ~~oil~~ cannabis product to be dispensed and the repackaging thereof;
6. The stocking or loading of devices used in the dispensing process;
7. The selling of the ~~oil~~ cannabis product to the registered patient, parent, ~~or~~ legal guardian or registered agent; and
8. The performance of any other task restricted to pharmacy technicians by the board's regulations.

~~D.~~ E. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation;

and extraction as authorized by the pharmaceutical processor, and duties associated with the dispensing of the oils products as authorized by the PIC or as otherwise authorized in law.

~~E. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.~~

~~F. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabis oil as authorized by the PIC.~~

~~G. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, and cannabis oil and shall ensure quality of the dispensed oils. Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC shall ensure security.~~

F. A pharmaceutical processor may employ individuals with less than two years of experience to perform cultivation-related duties under the supervision of an individual who has received a degree in a field related to the cultivation of plants or a certification recognized by the board or who has at least two years of experience cultivating plants.

G. A pharmaceutical processor may employ individuals with less than two years of experience to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

H. ~~Except for certain employee access to secured areas designated for cultivation and authorized by the PIC pursuant § 54.1-3442.6 of the Code of Virginia, at~~ At no time shall the dispensing area of a pharmaceutical processor operate or be accessed without a pharmacist on duty. At no time shall the cultivation and production area operate or be accessed without an employee on duty who satisfies the requirements for providing direct supervision for the activities in the respective areas.

I. No person shall be employed by or serve as an agent of a pharmaceutical processor or cannabis dispensing facility without being at least 18 years of age.

J. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor or cannabis dispensing facility unless such license or registration has been reinstated and is current and unrestricted.

18VAC110-60-180. Employee training.

A. All employees of a pharmaceutical processor or cannabis dispensing facility shall complete training prior to the employee commencing work at the pharmaceutical processor or cannabis dispensing facility. At a minimum, the training shall be in the following areas:

1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and cannabis oil products;
2. Procedures and instructions for responding to an emergency;
3. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and
4. Developments in the field of the medical use of cannabis oil products.

B. Prior to regular performance of assigned tasks, the employee shall also receive on-the-job training and other related education, which shall be commensurate with the tasks assigned to the employee.

C. The PIC and the responsible party shall assure the continued competency of all employees, in the respective areas for which they have oversight, through continuing in-service training that is provided at least annually, is designed to supplement initial training, and includes any guidance specified by the board.

D. The PIC and the responsible party shall be responsible for maintaining a written record documenting the initial and continuing training of all their respective employees that shall contain:

1. The name of the person receiving the training;
2. The dates of the training;
3. A general description of the topics covered;
4. The name of the person supervising the training; and
5. The signatures of the person receiving the training and the PIC or the responsible party.

E. When a change of pharmaceutical processor or cannabis dispensing facility PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.

F. A pharmaceutical processor or cannabis dispensing facility shall maintain the record documenting the employee training and make it available in accordance with regulations.

18VAC110-60-190. Pharmacy technicians; ratio; supervision and responsibility.

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor a cannabis dispensing facility designated for production or dispensing shall not exceed ~~four~~ six pharmacy technicians to one pharmacist.

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabis ~~or~~ products resulting from the actions of a pharmacy technician shall constitute grounds for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabis ~~or~~ product production or dispensing functions; and
2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent ~~or~~ legal guardian, or registered agent regarding (i) cannabis ~~or~~ products or other drugs either before or after cannabis ~~or~~ products have been dispensed or (ii) any medical information contained in a patient medication record;
2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabis ~~or~~ product or any other drug the patient may be taking;
3. Interpret the patient's clinical data or provide medical advice;
4. Determine whether a different formulation of cannabis ~~or~~ product should be substituted for the cannabis ~~or~~ product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or
5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

18VAC110-60-195. Responsibilities of the responsible party.

A. A person may only serve as the responsible party for one pharmaceutical processor at any one time. The responsible party shall be employed full-time in a managerial position at the location of the processor and shall be actively engaged in daily operations of the processor during normal hours of operation.

B. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the pharmaceutical processor.

C. The responsible party shall ensure compliance with all security measures to protect the Cannabis within the cultivation and production areas from diversion at all times and ensure that cultivation and production is performed in a safe and compliant manner, free of adulteration and misbranding.

D. The responsible party shall be responsible for ensuring that:

1. All employees practicing in the cultivation and production areas are properly trained;

2. All record retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and the cannabis products within the cultivation and production area are met; and

4. Any other required filings or notifications regarding the cultivation and production areas are made on behalf of the processor as set forth in regulation.

E. When the responsible party ceases practice at a pharmaceutical processor or no longer wishes to be designated as the responsible party, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the responsible party.

F. The outgoing responsible party shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, or cannabis products on hand in the cultivation and production areas on the date he ceases to be the responsible party, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A responsible party who is absent from practice for more than 30 consecutive days shall be deemed no longer be the responsible party. If the responsible party knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the responsible party that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new responsible party.

H. An application for a permit designating the new responsible party shall be filed with the required fee within 14 days of the original date of resignation or termination of the responsible party on a form provided by the board. It shall be unlawful for a pharmaceutical processor to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

18VAC110-60-200. Responsibilities of the PIC.

A. ~~No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy~~ The PIC of a pharmaceutical processor shall not serve as PIC of any other facility at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board. A person may serve simultaneously as the PIC for no more than two cannabis dispensing facilities located within the same health service area at any one time.

B. The PIC or the pharmacist on duty shall control all aspects of the practice in the dispensing area of the pharmaceutical processor or in a cannabis dispensing facility. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor or cannabis dispensing facility permit.

C. The PIC of a pharmaceutical processor ~~PIC~~ or cannabis dispensing facility shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;
2. All record retention requirements pertaining to the dispensing area met;
3. All requirements for the physical security of the Cannabis, ~~to include the seeds, any parts or extracts of the Cannabis plants and the cannabis oil~~ products are met;
4. The pharmaceutical processor or cannabis dispensing facility has appropriate pharmaceutical reference materials to ensure that cannabis oil products can be properly dispensed;
5. The following items are conspicuously posted in the pharmaceutical processor or cannabis dispensing facility in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, or legal guardians or registered agents:
 - a. Pharmaceutical processor permit or cannabis dispensing facility permit;
 - b. Licenses for all pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility; and
 - c. The price of all cannabis oil products offered by the pharmaceutical processor or cannabis dispensing facility; and
6. Any other required filings or notifications are made on behalf of the dispensing area of the pharmaceutical processor or the dispensing facility as set forth in regulation.

D. When the PIC ceases practice at a pharmaceutical processor or cannabis dispensing facility or no longer wishes to be designated as PIC, he shall immediately return the ~~pharmaceutical processor~~ permit to the board indicating the effective date on which he ceased to be the PIC.

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, ~~to include plants, extracts, or cannabis oil~~ products on hand in the dispensing area on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmaceutical processor or cannabis dispensing facility to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

Part V

Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

A. A pharmaceutical processor or cannabis dispensing facility shall only sell cannabis oil ~~only~~ products in a child-resistant, secure, and light-resistant container. Upon a written request from

the registered patient, parent, or legal guardian, or registered agent, the oil product may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

B. Only a pharmacist may dispense cannabis oil products to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board, or to a registered agent. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis oil products.

C. The PIC, or pharmacist, responsible party, or person who is qualified to provide supervision in accordance with 18VAC110-60-170 on duty shall restrict access to the pharmaceutical processor or cannabis dispensing facility to:

1. A person whose responsibilities necessitate access to the pharmaceutical processor or cannabis dispensing facility and then for only as long as necessary to perform the person's job duties; or
2. A person who is a registered patient, parent, or legal guardian, or registered agent, or a companion of the patient, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, or cannabis oil is products are stored.

D. All pharmacists and pharmacy technicians shall at all times while at the pharmaceutical processor or cannabis dispensing facility have their current license or registration available for inspection by the board or the board's agent.

E. While inside the pharmaceutical processor or cannabis dispensing facility, all ~~pharmaceutical processor~~ employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor or cannabis dispensing facility.

F. A pharmaceutical processor or cannabis dispensing facility shall be open for registered patients, parents, or legal guardians, or registered agents to purchase cannabis oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.

G. A pharmaceutical processor or cannabis dispensing facility that closes the dispensing area during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians, and registered agents of when the pharmaceutical processor or cannabis dispensing facility will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the cultivation, production, or dispensing area of the pharmaceutical processor or if a cannabis dispensing facility is or will be closed during its normal hours of operation for longer than two business days, the pharmaceutical processor or cannabis dispensing facility shall immediately notify the board.

H. A pharmacist shall counsel registered patients, parents, and legal guardians, and registered agents, if applicable, regarding the use of cannabis oil products. Such counseling shall include information related to safe techniques for proper use and storage of cannabis oil products and for disposal of the oils products in a manner that renders them nonrecoverable.

I. The pharmaceutical processor or cannabis dispensing facility shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy that shall be available to the board or the board's agent upon request.

18VAC110-60-215. Advertising.

A. A pharmaceutical processor or cannabis dispensing facility shall not advertise (i) through any means unless at least 85 percent of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time outside of regular school hours for elementary and secondary schools.

B. Advertising must accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility responsible for its content and include a statement that cannabis products are for use by registered patients only. Any advertisement for cannabis products that is related to the benefits, safety, or efficacy, including therapeutic or medical claims, of the cannabis product, shall:

1. Be supported by substantial clinical evidence or data; and
2. Include information on side effects or risks associated with the use of cannabis.

C. Advertising shall not:

1. Be misleading, deceptive, false or contain any statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;

2. Contain a statement, design, illustration, picture, or representation that:

- a. Encourages or represents the recreational use of cannabis;

- b. Targets or is attractive to persons younger than 18 years of age, including a cartoon character, a mascot, or any other depiction or image that is commonly used to market products to minors;

- c. Displays the use of cannabis, including the consumption, smoking, or vaping of cannabis;

- d. Encourages or promotes cannabis for use as an intoxicant; or

- e. Is obscene or indecent.

3. Display cannabis or cannabis product pricing except as allowed in 18VAC110-60-215

F.

4. Display cannabis products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place; and

5. Include coupons, giveaways of free cannabis products or distribution of merchandise that displays anything other than the facility name and contact information.

D. A pharmaceutical processor or cannabis dispensing facility may list their business in public phone books, business directories, search engines, or other places where it is reasonable for a business to maintain an informational presence of its existence, and a description of the nature of the business but shall not engage in the use of pop-up digital advertisements.

E. Any website or social media site owned, managed, or operated by a pharmaceutical processor or cannabis dispensing facility shall employ a neutral age-screening mechanism that verifies that the user is at least 18 years of age, including by using an age-gate, age-screen, or age verification mechanism.

F. A pharmaceutical processor or cannabis dispensing facility may display the following information on their website or social media site:

1. Name and location of the processor or facility;

2. Contact information for the processor or facility;

3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor or facility.

7. Educational materials regarding the use of cannabis products that are supported by substantial clinical evidence or data.

G. Communication and engagement for educational purposes with registered practitioners and registered patients, parents, legal guardians and registered agents, including the

dissemination of information permitted by 18VAC110-60-215 E and educational materials regarding the use of cannabis products available from the pharmaceutical processor or cannabis dispensing facility is allowed.

H. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility.

I. Signs placed on the property of a pharmaceutical processor or cannabis dispensing facility shall not:

1. Display imagery of cannabis or the use of cannabis or utilize long luminous gas-discharge tubes that contain rarefied neon or other gases;

2. Draw undue attention to the facility but may be designed to assist registered patients, parents, legal guardians and registered agents to find the pharmaceutical processor or cannabis dispensing facility; or

3. Be illuminated during non-business hours.

J. All outdoor signage must be in compliance with local or state requirements.

K. A pharmaceutical processor or cannabis dispensing facility shall not advertise at any sporting event or use any billboard advertisements.

L. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location.

18VAC110-60-220. Pharmaceutical processor or cannabis dispensing facility prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis ~~oil~~ products in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;
2. Sell, deliver, transport, or distribute Cannabis, including cannabis ~~oil~~ products, to any other facility except for wholesale distribution between pharmaceutical processors and to a cannabis dispensing facility pursuant to 18VAC110-60-251;
3. Produce or manufacture cannabis ~~oil~~ products for use outside of Virginia; or
4. Provide cannabis ~~oil~~ products samples.

B. No cannabis dispensing facility shall:

1. Dispense cannabis products in any place except the approved facility at the address of record on the application for the cannabis dispensing facility permit;
2. Sell, deliver, transport, or distribute cannabis products to any other facility, except that it may distribute cannabis products back to the pharmaceutical processor from which it obtained the products or distribute cannabis products between cannabis dispensing facilities; or
3. Provide cannabis products samples.

C. Except for certain employee access to secured areas designated for cultivation and production authorized by the PIG responsible party pursuant to § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor or cannabis dispensing facility shall be open or in operation, and no person shall be in the dispensing area of a pharmaceutical processor or in a cannabis dispensing facility, unless a pharmacist is on the premises and directly supervising the activity within the dispensing area of the pharmaceutical processor or a cannabis dispensing facility. At all other times, the dispensing area of the pharmaceutical processor or the cannabis dispensing facility shall be closed and properly secured.

~~G. D.~~ No pharmaceutical processor or cannabis dispensing facility shall sell anything other than cannabis oil products ~~from the pharmaceutical processor~~ except for devices for administration of dispensed products or hemp-based CBD products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280 D 2 and 3.

~~D.~~ A pharmaceutical processor shall not advertise cannabis oil products, except it may post the following information on websites:

~~1. Name and location of the processor;~~

~~2. Contact information for the processor;~~

~~3. Hours and days the pharmaceutical processor is open for dispensing cannabis oil products;~~

~~4. Laboratory results;~~

~~5. Product information and pricing; and~~

~~6. Directions to the processor facility.~~

E. No cannabis oil products shall be consumed on the premises of a pharmaceutical processor or cannabis dispensing facility, except for emergency administration to a registered patient.

F. No person except a pharmaceutical processor or cannabis dispensing facility employee or a registered patient, parent, or legal guardian, registered agent or a companion of a patient shall be allowed on the premises of a processor or facility with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis or cannabis oil products samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor or cannabis dispensing facility employee prior to entering the ~~pharmaceutical processor~~ or facility.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility and shall return the visitor identification badge to a ~~pharmaceutical processor~~ an employee upon exiting the ~~pharmaceutical processor~~ or facility.

3. All visitors shall log in and out. The pharmaceutical processor or cannabis dispensing facility shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor or cannabis dispensing facility to obtain a waiver from the board, the processor or facility shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor or cannabis dispensing facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

H. No cannabis ~~or~~ products shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor or cannabis dispensing facility, except that a registered parent ~~or~~ legal guardian, or registered agent or an agent of the processor or

cannabis dispensing facility may deliver cannabis oil products to the registered patient or in accordance with 18VAC110-60-310 A.

I. Notwithstanding the requirements of subsection F of this section, an agent of the board or local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor or cannabis dispensing facility if necessary to perform their governmental duties.

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis oil products, at the facility. The responsible party shall ensure all required inventories are performed in the cultivation and production areas, and the PIC shall ensure all required inventories are performed in the dispensing area. The inventory inventories shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, or pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. If a facility commences business with no Cannabis or cannabis products on hand, the pharmacist or responsible party shall record this fact as the initial inventory; and
2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis oil products, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

B. Upon commencing business, each pharmaceutical processor and ~~production facility~~ shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, and cannabis oil products in stock, that shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, or pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. ~~The record of all cannabis oil sold, dispensed, or otherwise disposed of shall show the date of sale; the name of the pharmaceutical processor; the registered patient, parent, or legal guardian to whom the cannabis oil was sold; the address of such person; and the kind and quantity of cannabis oil sold.~~

C. Upon commencing business, each cannabis dispensing facility shall maintain a perpetual inventory of all cannabis products received and dispensed that accurately indicates the physical count of each cannabis product on-hand at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each cannabis product at least monthly with a written explanation for any difference between the physical count and the theoretical count.

~~D.~~ E. The record of all cannabis oil products sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and address of the registered patient, parent, or legal guardian, or registered agent to whom the cannabis oil product was sold; the kind and quantity of cannabis oil product sold or disposed of; and the method of disposal.

~~D.~~ E. A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, and cannabis oil products on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC or responsible party may choose, so long as it is not more than one year following the prior year's inventory.

E. F. All inventories, procedures, and other documents required by this section shall be maintained on the premises and made available to the board or its agent.

F. G. Inventory records shall be maintained for three years from the date the inventory was taken.

G. H. Whenever any sample or record is removed by a person authorized to enforce state or federal law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabis ~~oil~~ products for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall:

~~1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days; and~~

~~2. Not~~ not maintain cannabis ~~oil~~ product in excess of the quantity required for normal, efficient operation;_

B. At no time shall a cannabis dispensing facility maintain cannabis products in excess of the quantity required for normal, efficient operation.

C. Items a pharmaceutical processor shall properly secure include Cannabis plants, seeds, parts of plants, extracts and cannabis products. A cannabis dispensing facility shall properly secure cannabis products. To secure these items a pharmaceutical processor and a cannabis dispensing facility shall:

3- 1. Maintain all Cannabis plants, seeds, parts of plants, extracts, and cannabis oil products in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;

4- 2. Store all cut parts of Cannabis plants, extracts, or cannabis oil products in an approved safe or approved vault within the pharmaceutical processor or cannabis dispensing facility and not sell cannabis oil products when the pharmaceutical processor or cannabis dispensing facility is closed;

5- 3. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabis oil products securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, or cannabis oil products;

6- 4. Keep all locks and security equipment in good working order; and

7- 5. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the dispensing area to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility.

6. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the cultivation and production areas to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor.

8- 7. Not allow keys to be left in the locks or accessible to non-pharmacists persons not authorized by the PIC or responsible party.

~~D. Access to keys or codes in areas of a pharmaceutical processor that are designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor. Employees, other than a pharmacist or person supervising cultivation-related or production-related activities at a processor, but designated by the PIC or responsible party may have the ability to unlock a secured area to gain entrance to perform required job duties, but only during hours of operation of the processor or dispensing facility. At no time shall these employees have access to the security system.~~

B. E. The pharmaceutical processor or cannabis dispensing facility shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, or cannabis ~~oil~~ products. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor or cannabis dispensing facility. The installation and the device shall be based on accepted alarm industry standards and subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other generally accepted and suitable device;
2. The device shall be monitored in accordance with accepted industry standards, be maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational;
3. The device shall fully protect the entire processor or facility and shall be capable of detecting breaking by any means when activated;

4. The device shall include a duress alarm, a panic alarm, and an automatic voice dialer; and

5. Access to the alarm system for the dispensing area of the processor or cannabis dispensing facility shall be restricted to the pharmacists working at the pharmaceutical processor or cannabis dispensing facility, and the system shall be activated whenever the pharmaceutical processor or facility is closed for business. Access to the security system in areas of a pharmaceutical processor that designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor.

G. F. A pharmaceutical processor or cannabis dispensing facility shall keep the outside perimeter of the premises well-lit. A processor or facility shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, or cannabis ~~oil~~ products and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

1. The processor or facility shall direct cameras at all approved safes, approved vaults, dispensing areas, or cannabis ~~oil~~ products sales areas, and any other area where Cannabis plants, seeds, extracts, or cannabis ~~oil~~ products are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor or facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

2. The video system shall have:

a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an

- alert to the processor or facility within five minutes of the failure, either by telephone, email, or text message;
- b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image, live or recorded;
 - c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
 - d. The ability to remain operational during a power outage;
3. All video recordings shall allow for the exporting of still images in an industry standard image format. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmaceutical processor or cannabis dispensing facility shall erase all recordings prior to disposal or sale of the facility; and
4. The processor or facility shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor or facility is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor or facility shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor or cannabis dispensing facility PIC that it is not necessary to retain the recording.

D. G. The processor or facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every six months.

E. H. A pharmaceutical processor or cannabis dispensing facility shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor or facility shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor or facility. The pharmaceutical processor or cannabis dispensing facility shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

F. I. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, or cannabis oil products has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

18VAC110-60-250. Requirements for the storage and handling of Cannabis or cannabis oil products.

A. A pharmaceutical processor or cannabis dispensing facility shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature, and humidity as defined in 18VAC110-60-10 and space, equipment, and security conditions for the cultivation of Cannabis and the production and dispensing of cannabis oil products;
2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabis oil products, that is are outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or

breached, until such Cannabis plants, seeds, parts of plants, extracts, or cannabis oil products are destroyed;

3. Be maintained in a clean, sanitary, and orderly condition; and

4. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. A pharmaceutical processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabis oil products. These shall include policies and procedures that:

1. Restrict movement between compartments;

2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;

3. Require pocketless clothing for all ~~production facility~~ employees working in an area containing Cannabis plants, seeds, and extracts, including cannabis oil and cannabis products; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, and cannabis oil products.

C. A cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper dispensing of cannabis products, including a requirement for pocketless clothing for all facility employees working in an area containing cannabis products.

D. The PIC and responsible party of a pharmaceutical processor or the PIC of a cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including the seeds, parts of plants, extracts, and the cannabis oil products, as applicable. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. Pharmaceutical processors and cannabis dispensing facilities shall include in their written policies and procedures a process for the following:

1. Handling mandatory and voluntary recalls of cannabis oil products. The process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor or cannabis dispensing facility to (i) remove defective or potentially defective cannabis oil products from the market or (ii) promote public health and safety by replacing existing cannabis oil products with improved products or packaging;
 2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;
 3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, and cannabis oil products, is segregated from all other Cannabis, seeds, parts of plants, extracts, and cannabis oil products and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, and cannabis oil product disposition;
- and

4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, and cannabis oil ~~product~~ products are used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

D- E. The pharmaceutical processor shall store all Cannabis, including seeds, parts of plants, extracts, and cannabis oil products, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss; shall make Cannabis, including the seeds, parts of plants, extracts, and cannabis oil products accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist, responsible party, or other person authorized by the responsible party to supervise cultivation and production at the processor shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, and cannabis oil products, inside an area or building that affords adequate security.

F. The cannabis dispensing facility shall store all cannabis products in such a manner as to prevent diversion, theft, or loss; shall make cannabis products accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the cannabis products to their secure location at the completion of the dispensing or at end of the scheduled business day.

18VAC110-60-251. Wholesale distribution of cannabis oil products.

A. Cannabis oil, cannabis products, botanical cannabis, and usable cannabis from a batch that passed the required tests listed in 18VAC110-60-300 G and H microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests, and, for botanical cannabis, the water activity and moisture content, and are packaged and labeled for sale with an appropriate

expiration date in accordance with 18VAC110-60-300 | may be wholesale distributed between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility.

B. Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 | may be wholesale distributed between cannabis dispensing facilities

C. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor or cannabis dispensing facility distributing the product and the processor or cannabis dispensing facility receiving the product, and (iii) the kind and quantity of product being distributed, and (iv) the batch and lot identifying information to include harvest date, testing date, processing or manufacturing date and expiration date. The record of the transaction shall be maintained by the distributing pharmaceutical processor or cannabis dispensing facility with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or facility receiving the product in its records of receipt. Such records shall be maintained by each processor or facility for three years in compliance with 18VAC110-60-260.

D. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared upon request to registered patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

E. A pharmaceutical processor or cannabis dispensing facility wholesale distributing products shall store and handle products and maintain policies and procedures, to include a process for

executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

F. If a pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products uses an electronic system for the storage and retrieval of records related to distributing cannabis products, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

18VAC110-60-260. Recordkeeping requirements.

A. If a pharmaceutical processor or cannabis dispensing facility uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabis ~~oil~~ products, as applicable, the pharmaceutical processor or cannabis dispensing facility shall use a system that:

1. Guarantees the confidentiality of the information contained in the system;
2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist or responsible party;
and
3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

B. All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of three years and shall be made available to the board upon request.

18VAC110-60-270. Reportable events; security.

A. Upon becoming aware of (i) diversion, theft, loss, or discrepancies identified during inventory; (ii) unauthorized destruction of any cannabis ~~oil~~ products; or (iii) any loss or unauthorized alteration of records related to cannabis ~~oil~~ products or qualifying patients, a

pharmacist, responsible party, or pharmaceutical processor, or cannabis dispensing facility shall immediately notify appropriate law-enforcement authorities and the board.

B. A pharmacist, or responsible party, pharmaceutical processor, or cannabis dispensing facility shall provide the notice required by subsection A of this section to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabis or product diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist, responsible party, or processor, or facility shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacist, responsible party, or pharmaceutical processor, or cannabis dispensing facility shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:

1. An alarm activation or other event that requires a response by public safety personnel;
2. A breach of security;
3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
4. Corrective measures taken if any.

D. A pharmacist, responsible party, or pharmaceutical processor, or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony or any offense referenced in § 54.1-3442.6 of the Code of Virginia.

Part VI

Cultivation, Production, and Dispensing of Cannabis Oil Products

18VAC110-60-280. Cultivation and production of cannabis oil products.

A. No cannabis oil products shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

B. Cultivation methods for Cannabis plants and extraction methods used to produce the cannabis oil products shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, or cannabis oil products not in compliance with this section shall be deemed adulterated.

D. A pharmaceutical processor may acquire oil from industrial hemp extract for the purpose of formulating such oil extract with cannabis plant extract into allowable dosages of cannabis oil provided:

1. The pharmaceutical processor acquires the oil from industrial hemp extract processed in Virginia and in compliance with state or federal law from a registered industrial hemp dealer or processor;
2. The oil from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements applicable to cannabis plant extract as verified by testing performed by a laboratory located in Virginia and in compliance with state law; and
3. The industrial hemp dealer or processor provides such third-party testing results to the pharmaceutical processor before oil from industrial hemp is acquired.

E. A pharmaceutical processor acquiring oil from industrial hemp extract shall ensure receipt of a record of the transaction that shows the date of distribution, the names and addresses of the registered industrial hemp dealer or processor distributing the product and the pharmaceutical processor receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be maintained by the pharmaceutical processor with its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years.

F. A pharmaceutical processor shall maintain policies and procedures for the proper storage and handling of oil from industrial hemp extract, to include a process for executing or responding to mandatory and voluntary recalls in a manner that complies with 18VAC110-60-250.

G. No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate.

18VAC110-60-285. Registration of products.

A. A pharmaceutical processor shall assign a brand name to each product of cannabis oil. The pharmaceutical processor shall register each brand name with the board on a form prescribed by the board prior to any dispensing and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);
2. Tetrahydrocannabinol acid (THC-A);
3. Cannabidiols (CBD); and
4. Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 90% to 110%.

C. The board shall not register any brand name that:

1. Is identical to or confusingly similar to the name of an existing commercially available product;
2. Is identical to or confusingly similar to the name of an unlawful product or substance;
3. Is confusingly similar to the name of a previously approved cannabis ~~oil~~ product brand name;
4. Is obscene or indecent;
5. May encourage the use of marijuana or cannabis ~~oil~~ products for recreational purposes;
6. May encourage the use of cannabis ~~oil~~ products for a disease or condition other than the disease or condition the practitioner intended to treat;
7. Is customarily associated with persons younger than the age of 18; or
8. Is related to the benefits, safety, or efficacy of the cannabis ~~oil~~ product unless supported by substantial evidence or substantial clinical data.

18VAC110-60-290. Labeling of batch of cannabis ~~oil~~ products.

A. Cannabis ~~oil~~ products produced as a batch shall not be adulterated.

B. Cannabis ~~oil~~ products produced as a batch shall be:

1. Processed, packaged, and labeled according to the U.S. Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 CFR Part 111; and

2. Labeled with:

- a. The name and address of the pharmaceutical processor;
- b. The brand name of the cannabis oil product that was registered with the board pursuant to 18VAC110-20-285;
- c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;
- d. The date of testing and packaging;
- e. The expiration date which shall be six months or less from the date of packaging, unless supported by based on stability testing;
- f. The quantity of cannabis oil products contained in the batch;
- g. A terpenes profile and a list of all active ingredients, including:
 - (1) Tetrahydrocannabinol (THC);
 - (2) Tetrahydrocannabinol acid (THC-A);
 - (3) Cannabidiol (CBD); and
 - (4) Cannabidiolic acid (CBDA); and

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;
- h. For cannabis oil products, a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis; and

i. For botanical cannabis products, a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, pesticide chemical residue analysis, water activity and moisture content, and the potency.

18VAC110-60-300. Laboratory requirements; testing.

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis oil products unless such laboratory:

1. Is independent from all other persons involved in the cannabis oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, cannabis dispensing facility, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis oil products; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the ISO/IEC 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration

method utilized to perform a Cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use nonaccredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use nonaccredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize non-accredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within twenty-four hours. The laboratory shall immediately stop handling, testing or analyzing Cannabis for pharmaceutical processors.

5. Complies with a transportation protocol for transporting Cannabis or cannabis products to or from itself or to or from pharmaceutical processors.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue, and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

C. A pharmaceutical processor shall make a sample available from each harvest batch of botanical cannabis product to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue, water activity and moisture content, and (ii) conduct an active ingredient analysis and terpenes profile. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The sample must be representative of the entire batch to include selection from various points in the batch container lot and be of sufficient sample size to allow for analysis of all required tests.

D. From the time that a batch of cannabis oil product has been homogenized for sample sampled for testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

E. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

F. The processor shall require the laboratory to immediately return or properly dispose of any cannabis oil products and materials upon the completion of any testing, use, or research.

G. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

1. For purposes of the microbiological test, a cannabis oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

- a. Tetrahydrocannabinol (THC);
- b. Tetrahydrocannabinol acid (THC-A);
- c. Cannabidiols (CBD); and
- d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. ~~If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.~~

H. If a sample of botanical cannabis product does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity or moisture content test based on the standards set forth in this subsection, the batch may be remediated. Once remediated, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity and moisture content, and an active ingredient analysis and terpenes profile shall be conducted. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all testing standards set forth in 18VAC110-60-300 G.

1. For purposes of the microbiological test, a botanical cannabis product sample shall be deemed to have passed if it satisfies the standards set forth in the most current American Herbal Pharmacopoeia Cannabis Inflorescence Standards of Identity, Analysis, and Quality Control.

2. For purposes of the mycotoxin test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

<u>Test Specification</u>	
<u>Aflatoxin B1</u>	<u><20 ug/kg of Substance</u>
<u>Aflatoxin B2</u>	<u><20 ug/kg of Substance</u>
<u>Aflatoxin G1</u>	<u><20 ug/kg of Substance</u>
<u>Aflatoxin G2</u>	<u><20 ug/kg of Substance</u>
<u>Ochratoxin A</u>	<u><20 ug/kg of Substance</u>

3. For purposes of the heavy metal test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

<u>Metal</u>	<u>Limits - parts per million (ppm)</u>
<u>Arsenic</u>	<u><10 ppm</u>

<u>Cadmium</u>	<u><4.1 ppm</u>
<u>Lead</u>	<u><10 ppm</u>
<u>Mercury</u>	<u><2 ppm</u>

4. For purposes of the pesticide chemical residue test, a sample of botanical cannabis product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the botanical cannabis product shall be tested for:

- a. Total tetrahydrocannabinol (THC); and
- b. Total cannabidiol (CBD).

6. For the purposes of water activity and moisture content for botanical cannabis, the product shall be deemed to have passed if the water activity rate does not exceed 0.65Aw and the moisture content does not exceed 15 percent.

I. If a sample of cannabis oil product passes the required tests listed in 18VAC110-60-300 G and H ~~microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test~~, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products, except stability testing shall not be required for cannabis oil products if the pharmaceutical processor assigns an expiration date of six months or less from the date of packaging.

J. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the ~~microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test, and, for botanical cannabis, water activity or~~

~~moisture content~~, required tests listed in 18VAC110-60-300 G and H at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

K. Each pharmaceutical processor or cannabis dispensing facility shall have such laboratory results available upon request to registered patients, parents or legal guardians, registered agents, and registered practitioners who have certified qualifying patients, the board, or an agent of the board.

18VAC110-60-310. Dispensing of cannabis oil products.

A. A pharmacist in good faith may dispense cannabis oil products to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of cannabis oil products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view, in person or by audiovisual means, a current photo identification of the patient, parent, or legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis oil products to the registered patient.

2. The A pharmacist or pharmacy technician employed by the processor or cannabis dispensing facility shall make and maintain for three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible and shall maintain it on site or by electronic means for two years.

3. Prior to any subsequent dispensing, the pharmacist, or pharmacy technician, or delivery agent shall view verify that the current written certification and on file has not expired. An employee or delivery agent shall view a current photo identification and current registration of the patient, parent, or legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the pharmaceutical processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis or product. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis or products at any time except that no registered patient, parent, or legal guardian, or registered agent shall receive more than a 90-day supply of cannabis or products for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. However, no more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. In determining the appropriate amount of cannabis product to be dispensed to a patient, a pharmacist shall consider all cannabis products dispensed and adjust the amount dispensed accordingly.

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of or cannabis product that contains:

1. A serial number assigned to the dispensing of the or product;
2. The brand name of cannabis or product that was registered with the board pursuant to 18VAC110-60-285 and its strength;
3. The serial number assigned to the or product during production;
4. The date of dispensing the cannabis or product;

5. The quantity of cannabis oil products dispensed;
6. A terpenes profile and a list of all active ingredients, including:
 - a. Tetrahydrocannabinol (THC);
 - b. Tetrahydrocannabinol acid (THC-A);
 - c. Cannabidiol (CBD); and
 - d. Cannabidiolic acid (CBDA);

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis, and for botanical cannabis, the water activity and moisture content analysis;
8. The name and registration number of the registered patient;
9. The name and registration number of the certifying practitioner;
10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;

~~11.~~ 12. The name or initials of the dispensing pharmacist;

~~12.~~ 13. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;

~~13.~~ 14. Any necessary cautionary statement; and

14. 15. A prominently printed expiration date based on stability testing and the pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. A pharmaceutical processor shall not label cannabis oil products as "organic" unless the Cannabis plants have been organically grown and the cannabis oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.

E. The cannabis oil products shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

F. No person except a pharmacist or a pharmacy technician operating under the direct supervision of a pharmacist shall alter, deface, or remove any label so affixed.

G. A pharmacist shall be responsible for verifying the accuracy of the dispensed oil product in all respects prior to dispensing and shall document that each verification has been performed.

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis oil products in treating the registered patient's diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis oil products to a registered patient, parent, or legal guardian, or registered agent if the pharmacist suspects that dispensing cannabis oil products to the registered patient, parent, or

legal guardian, or registered agent may have negative health or safety consequences for the registered patient or the public.

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor or cannabis dispensing facility shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor or cannabis dispensing facility shall distribute the written policies and procedures to all pharmaceutical processor or cannabis dispensing facility employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor or cannabis dispensing facility. The policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and
2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor or cannabis dispensing facility shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor or cannabis dispensing facility PIC shall:

1. Inform pharmaceutical processor or cannabis dispensing facility employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor or facility employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;
3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and
4. Create a record of every quality assurance review. This record shall contain at least the following:
 - a. The date of the quality assurance review and the names and titles of the persons performing the review;
 - b. The pertinent data and other information relating to the dispensing error reviewed;
 - c. Documentation of contact with the registered patient, parent, ~~or~~ legal guardian, or registered agent, where applicable, and the practitioner who certified the patient;
 - d. The findings and determinations generated by the quality assurance review; and
 - e. Recommended changes to pharmaceutical processor or cannabis dispensing facility policy, procedure, systems, or processes if any.

C. A pharmaceutical processor or cannabis dispensing facility shall maintain for three years a copy of the pharmaceutical processor's or cannabis dispensing facility's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

18VAC110-60-321. Devices, hemp-based CBD products, and inert product samples.

A. A pharmaceutical processor or cannabis dispensing facility may have for sale, on-site, devices intended for the administration of dispensed cannabis products and hemp-based CBD

products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280 D 2 and 3.

B. The pharmaceutical processor or cannabis dispensing facility may use and distribute inert product samples that do not contain any active cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility without the need for a written certification. Such inert product samples may not be sold or further distributed.

18VAC110-60-330. Disposal of cannabis oil products.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated green waste, extracts, and cannabis products, as applicable. Green waste includes Cannabis plants, including seeds, and parts of plants, extracts, or cannabis oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabis oil nonrecoverable. Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render ~~it~~ the mixture materially inactive and unrecognizable. Once rendered unrecognizable, green waste shall be considered agricultural waste and may be disposed of accordingly.

B. The destruction and disposal of green waste, extracts, and cannabis oil products, as applicable, shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor a pharmacist and at least one other employee of the pharmaceutical processor or cannabis dispensing facility, respectively, and shall be conducted under video surveillance. The persons ~~destroying and~~ disposing of the green waste, extracts, or cannabis oil products shall maintain and make available a separate record of each ~~such~~ occurrence of destruction and disposal indicating:

1. The date and time of destruction and disposal;

2. The manner of destruction and disposal;

3. The name and quantity of ~~cannabis oil~~ cannabis product and green waste destroyed
and disposed of; and

4. The signatures of the persons destroying or and disposing of the green waste, extracts,
or cannabis oil products.

C. The record of destruction and disposal shall be maintained at the pharmaceutical processor
or cannabis dispensing facility for three years from the date of destruction and disposal.